In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 9, 2022

ROBERT GALANTE,	*	UNPUBLISHED
Petitioner,	*	No. 18-1933V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Intradermal Influenza ("flu") Vaccine; Shoulder Pain and Dysfunction.
Respondent.	*	

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for petitioner.
Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On December 18, 2018, Robert Galante ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that as a result of receiving an intradermal influenza ("flu") vaccine on September 7, 2016, in his left arm he suffered a shoulder injury related to vaccine administration ("SIRVA") that was caused in fact by the flu vaccination. Petition (ECF No. 1). After a review of the record as a whole, including expert reports, medical records, affidavits, entitlement hearing testimony, and briefings by the parties, and for the reasons set forth below, I find that petitioner is entitled to compensation.

I. Procedural History

Petitioner filed his petition for compensation on December 18, 2018, alleging he sustained a left shoulder injury related to vaccine administration ("SIRVA") as a result of

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

receiving an intradermal influenza ("flu") vaccination on September 7, 2016. Petition at Preamble. The case was initially referred to the Special Processing Unit ("SPU"), with former Chief Special Master Dorsey as the presiding Special Master. *See* SPU Initial Order (ECF No. 5). The case was assigned to my docket on March 13, 2019. *See* Notice of Reassignment (ECF No. 9).

On April 3, 2019, I held a status conference in this case, and ordered petitioner to file additional medical records, affidavits, and other evidence to establish onset of his shoulder injury. (ECF No. 10). On June 3, 2019, petitioner filed a statement of completion after filing updated medical records and affidavits. (ECF Nos. 11, 13, 14).

On August 30, 2019, petitioner filed expert reports by Dr. Eric Gershwin,[3] an immunologist, and Dr. Russell Huffman,[4] an orthopaedic surgeon. Petitioner's Exhibit ("Pet. Ex.") 10; Pet. Ex. 11 (ECF No. 20). Dr. Gershwin stated that "there is evidence that intradermal vaccines can cause a systemic inflammatory response." Pet. Ex. 10 at 1. Dr. Huffman stated that Mr. Galante had both a local and regional response causing restriction of motion secondary to pain. Tr. 131.

On January 6, 2020, respondent filed an expert report by Dr. Paul J. Cagle,[5] an orthopaedic surgeon. Respondent's Exhibit ("Resp. Ex.") A (ECF No. 23). On February 6, 2020, respondent filed an expert report by Dr. Harry W Schroeder, Jr., MD,[6] an immunologist. Resp.

[3] Dr. Gershwin graduated with a Bachelor of Science degree in mathematics from Syracuse University in 1966 and a medical degree from Stanford University in 1971. Pet. Ex. 22 at 1. He completed an internship and residency at Tufts-New England Medical Center, then served as a clinical associate in immunology at the National Institutes of Health. *Id.* at 2. In 1975, Dr. Gershwin joined the University of California Davis (UC Davis) School of Medicine to start its immunology program. *Id.* at 1. He is currently the Jack and Donald Chia Professor and a Distinguished Professor of Medicine in the divisions of Rheumatology/ Allergy and Clinical Immunology at UC Davis. *Id*. Dr. Gershwin is licensed to practice medicine in the state of California. He is board-certified in internal medicine, rheumatology, allergy, and clinical immunology. *Id.* at 2. Dr. Gershwin highlighted that he has been awarded an honorary doctorate degree by the University of Athens, home of the Hippocratic Oath, for lifetime achievement in immunology. *Id*. at 1.

[4] Dr. Huffman is a shoulder and elbow surgeon and an Associate Professor of Orthopedic Surgery and Director of the Shoulder and Elbow Surgery Fellowship at the University of Pennsylvania Medical Center. Pet. Ex. 23 at 1. Dr. Huffman earned his M.D. at Duke University School of Medicine, completed his surgical internship and orthopaedic surgery residency at the University of California, San Francisco, and completed shoulder and elbow fellowships at the University of Southern California and Mayo Clinic. *Id*. He has authored over 100 publications and lectured nationally and internationally. *Id*. He researches shoulder and elbow issues and has diagnosed and treated patients with SIRVA for over eight years. *Id*. Dr. Huffman is currently investigating a SIRVA protocol at the University of Pennsylvania. *Id.*

[5] Dr. Paul J. Cagle is an orthopaedic surgeon who serves as an Assistant Professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. Resp. Ex. B at 1. Dr. Cagle received his medical degree from the Loyola University Chicago Stritch School of Medicine. *Id*. He did a residency in orthopaedic surgery at the University of Minnesota Academic Health Center and Medical School from 2008-2013. *Id.* He board certified in orthopaedic surgery. *Id.* Prior to working at Mount Sinai, Dr. Cagle was an assistant professor and interim chair of the Department of Orthopaedic Surgery at Southern Illinois University School of Medicine. *Id.* He has published numerous articles in peer reviewed journals. *Id*. at 3-14.

[6] Dr. Schroeder is currently a professor of medicine, microbiology and genetics at the School of Medicine at the University of Alabama ("UAB"). Resp. Ex. D at 1. Dr. Schroeder received his undergraduate degree from Texas A&M in 1974 and his medical degree from Baylor College of Medicine in 1981. Resp. Ex. B at 2. Additionally, he

Ex. C (ECF No. 26). The same day respondent filed his Rule 4(c) report recommending that compensation be denied. Resp. Report (ECF No. 27). Respondent noted that the flu vaccine petitioner received on September 7, 2016, was administered intradermally and not intramuscularly and therefore is not eligible for a Table SIRVA. *Id*. at 6-7. Respondent asserted that petitioner must provide a medical theory for how a vaccine administered intradermally could cause a left shoulder injury. *Id*. Respondent asserted that petitioner has not provided sufficiently reliable, preponderant evidence of causation that satisfies the elements of *Althen*. *Id*. at 7. Specifically, respondent asserted that there is no evidence in the record of systemic inflammatory response to the vaccination in question. *Id*. at 7-8.

On March 11, 2020, I held a Rule 5 status conference in this case and issued a Rule 5 order ordering petitioner to convey a modest demand to respondent. Rule 5 Order (ECF No. 28). On April 14, 2020, petitioner filed a supplemental expert report by Dr. Gershwin. Pet. Ex. 24 (ECF No. 29). On May 14, 2020, petitioner filed a status report indicating that he provided respondent with a settlement demand that day. (ECF No. 31). On June 19, 2020, respondent submitted a status report indicating that he will not entertain settlement negotiations. (ECF No. 32). The same day I ordered petitioner to file a supplemental expert report.

On August 3, 2020, petitioner filed a supplemental expert report by Dr. Russell Huffman. Pet. Ex. 36 (ECF No. 33). On November 3, 2020, I held a status conference and ordered the parties to propose dates for an entitlement hearing. (ECF No. 35). On January 11, 2021, I issued a hearing order to schedule an entitlement hearing on April 15-16, 2021. Hearing Order (ECF No. 40).

On February 11, 2021, petitioner filed a pretrial memorandum. (ECF No. 45). On March 12, 2021, respondent filed prehearing submissions. (ECF No. 46). On April 1, 2021, respondent filed a Motion in Limine to exclude the testimony of Melissa Dell'Orfano, the vaccine administrator. (ECF No. 51). Petitioner filed a response to the motion on April 2, 2021, urging the court to deny respondent's motion. (ECF No. 53). On April 7, 2021, I issued a hearing order denying respondent's motion, and ordering the fact witnesses and expert immunologists to testify on April 15, 2021, and the expert orthopedists to testify at a later date. Hearing Order (ECF No. 54). The entitlement hearing occurred on April 15, 2021, and I issued a hearing order for the continuation of the entitlement hearing to be completed on June 10, 2021. Hearing Order (ECF No. 55).

On May 26, 2021, I held a status conference regarding the six cases involving intradermal flu vaccines, and respondent objected to the prospect of any mandatory omnibus proceeding and expressed the desire to move forward with each case individually. Order (ECF No. 58). On October 15, 2021, petitioner filed his post hearing brief. Pet. Brief (ECF No. 63). On January 26,

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received his PhD in cell biology in 1979. *Id.* Dr. Schroeder did his residency at the University of Kentucky Medical Center from 1982-1984. *Id.* He has been teaching at the University of Alabama since July 1988. *Id.* Additionally, Dr. Schroeder is the editor of the textbook *Clinical Immunology: Principles and Practices*, and he has conducted clinical practice at UAB evaluating patients with immune mediated diseases. Resp. Ex. A at 1. Finally, Dr. Schroeder is active in academic research. Resp. Ex. B at 11-15. Dr. Schroeder was admitted as an expert in immunology during the hearing. Tr. 73.

2022, respondent filed his post hearing brief. Resp. Brief (ECF No. 66). On March 18, 2022, petitioner filed a post hearing brief reply. Pet. Reply (ECF No. 69).

The matter is now ripe for adjudication.

II. Petitioner's Medical History

a. Medical Records

At an appointment with his primary care physician ("PCP") on September 7, 2016, Mr. Galante complained of ongoing right knee pain over the last six months, with a "pain intensity of 8/10." Pet. Ex. 1 at 19. It was noted under "Assessment and Plan," that the findings were indicative of overuse injury with meniscus injury, and petitioner was referred to an orthopedist. *Id*. at 21. During that appointment petitioner received the intradermal flu vaccine administered in his "left arm (upper)." *Id*. at 20.

On September 30, 2016, petitioner presented to orthopedic surgeon, Dr. Thomas J. Gill, M.D., complaining of right knee pain, starting six months ago. Pet. Ex. 2 at 8. Petitioner was assessed to have a medial meniscus tear, and Dr. Gill ordered an MRI. *Id*. at 9. Following the MRI, petitioner returned to Dr. Gill and the ongoing plan was physical therapy. *Id*. at 7. Petitioner began physical therapy for his right knee on October 20, 2016. Pet. Ex. 4 at 5.

On January 20, 2017, petitioner was seen by his PCP, Dr. Jennifer Powell, D.O., with complaints of left shoulder pain, that started "after having [a] flu shot in September, [and] ongoing for the past [four] months." Pet. Ex. 1 at 14. Petitioner stated that he took Advil at night because it "hurts more at night," he was having problems with his range of motion, no acute swelling, difficulty laying on his left arm, and no acute fever or chills. *Id*. at 14. Dr. Powell wrote that petitioner "was found to have limited range of motion with concerns of possible rotator cuff injury from the influenza vaccine." *Id*. at 17.

Petitioner returned to Dr. Gill's office on January 27, 2017, and was seen by Brian Petrone, PA-C for "lateral shoulder pain after the flu shot." Pet. Ex. 2 at 6. Petitioner stated, "he has always had mild pain to the shoulder with [decreased range of motion] and [decreased] strength." *Id*. [7] Further, his general pain and range of motion did not improve. *Id*. It was recorded that petitioner "is not progressing," with "worsening pain despite conservative treatment." *Id*. An MRI was recommended to check for "[rotator cuff tear]." *Id*.

The same day, January 27, 2017, petitioner had an MRI of his left shoulder. Pet. Ex. 3 at 3. The MRI showed moderate degenerative changes with "mild glenohumeral joint chondrosis with degeneration of the superior/posterosuperior labrum and possible tearing of the superior labrum…mild biceps long head and minimal supraspinatus tendinosis without discrete tearing…AC joint degenerative changes." *Id*. On February 3, 2017, petitioner returned to Dr. Gill to discuss surgical options regarding his right knee pain. Pet. Ex. 2 at 5. Dr. Gill also reported that petitioner "had a shoulder [MRI] last Friday for left shoulder pain which may be

[7] Petitioner testified that he "emphatically" stated that his shoulder pain began "immediately following the flu shot." Tr. 22.

related to a flu shot [on] 9/16." *Id*. Dr. Gill noted that petitioner wanted to pursue a right knee scope and for his left shoulder he will start physical therapy for "[rotator tear cuff] strengthening." *Id*.

On February 28, 2017, petitioner underwent a right-knee arthroscopy to correct a medial and lateral meniscal tear. Pet. Ex. 28 at 2. During a post-surgery physical therapy appointment on March 9, 2017, petitioner reported "[left] shoulder pain that began in fall 2016 after getting a vaccine, pain worsened as time passed. Patient got an MRI that showed the bursa was affected during administration of the shot. His shoulder has ached since the shot." Pet. Ex. 4 at 33. At his next physical therapy appointment on March 15, 2017, it was noted that "he shoveled snow yesterday – no swelling after, some soreness this morning." *Id*. at 37.

On March 28, 2017, at another post-surgery physical therapy session it was noted that petitioner reported shoulder pain and that it "has been getting worse. *Id*. at 41. The physical therapy note [also noted "[moderate]-[severe] tenderness [of the] posterior shoulder," and the "[left] shoulder pain consistent with rotator cuff tendinopathy." *Id*. On April 11, 2017, petitioner started shoulder muscle energy technique "for rotator cuff tendinopathy." *Id*.

To address the left shoulder pain, petitioner initiated physical therapy for his shoulder on October 24, 2017. Pet. Ex. 4 at 50. Petitioner reported the "mechanism of injury was secondary to getting a flu shot too high up on the shoulder." *Id*. Further he expressed his frustration regarding his shoulder pain and that it "has been going on for so long," and "can only sleep 1-2 hours at a time currently. *Id*. at 51. Under "Assessment," the physical therapist noted that petitioner "presents with signs and symptoms consistent with a diagnosis of [left] shoulder pain presenting as contractile pathology." He participated in a total of nine physical therapy sessions, between October 31, 2017, and December 19, 2017. Petitioner reported in the final session that his shoulder does not bother him during a workout, but "bothers him when he tries to fall asleep." *Id*. at 54-72. During cross-examination, petitioner was asked what types of workouts he was able to complete without his shoulder giving him pain. Tr. 36-37. Petitioner testified that his workouts include riding a bicycle and a lot of walking. *Id*. at 37. Petitioner further explained he used to weightlift and stopped in September 2016, and into the fall through winter of 2016 and 2017. *Id*. at 38.

b. Hearing Testimony

1. Testimony of Petitioner

During the hearing held on April 15-16, 2021, petitioner testified that on September 7, 2016, he went to Hallmark Medical Associates in Malden, Massachusetts to see his primary care physician for ongoing knee pain. Transcript ("TR.") at 6. He stated that he was seated in an exam room, a "rather low chair," and the nurse administered the intradermal flu vaccination on the left shoulder. Tr. 7-8. He testified that the vaccination was administered "kind of high, mid to back." Id. at 8. The Court asked petitioner to put his finger on the end of the acromion bone, "the shoulder bone that comes to the end of your shoulder," and asked how many inches below the vaccine was administered. *Id*. Petitioner testified that it was about an inch and a half or so from the acromion bone. *Id*. at 8-9.

Petitioner recalled that when he arrived at the appointment, he did not have any pain in his left shoulder. Tr. 9. But when he left, he was experiencing left shoulder pain. Tr. 9. He stated that his pain level was a 9 out of 10 and when he got home, he immediately took pain medication and iced his left shoulder. Tr. 10. Petitioner testified that he was unable to get a full night's sleep that night because he "could still feel the stinging" in his arm. *Id*. He testified that in the days following September 7, 2016, the pain persisted and stayed about the same, with constant stinging, redness, hot to the touch, lasting for over a month, and with a hard lump that got larger "for a couple days and then it started to eventually disappear." *Id*. at 11-12. Further, the lump was present for about three weeks to a month. *Id*. at 13.

On cross examination, petitioner was asked if the pain in his shoulder was similar to pain he had experienced after past immunizations. Tr. 39. Petitioner stated, "Upon immediately receiving the flu shot, it was similar. But this was a little bit more painful than the normal flu shot." *Id.* Petitioner was asked why he did not report his left shoulder pain to his orthopedic surgeon Dr. Gill during a September 30, 2016. Tr. 30-31. Petitioner stated that the September 30th appointment was for his knee pain, and he felt "a little embarrassed that [he] had received the flu shot and didn't want to discuss the pain over a flu shot with a couple of guys." *Id*. at 31.

Petitioner stated that immediately following the shot he was having difficulty moving his left shoulder, and it lasted "for quite a while, even a few years," and as a result he did not like to raise his left shoulder joint. Tr. 13. When asked what at-home remedies helped with the symptoms, petitioner explained that he took Advil and continued icing it to this day, April 15, 2021. Tr. 14. He stated that this pain made it hard to do day-to-day chores, and while petitioner had retired from his job as a biomedical engineer, he had recently started an LLC in the field of clinical cardiac devices. Tr. 14-15. When asked how his symptoms impacted his ability to perform activities in the LLC, he explained that he "just didn't have the drive that [he] used to because of a little bit of the fatigue from not sleeping primarily." Tr. 15. He also cancelled an annual ski trip because of the pain in his left shoulder. *Id*. at 16.

Petitioner testified that by January 2017 his left shoulder pain was so disruptive to his sleep that his wife urged him to seek treatment. Tr. 17. Petitioner stated that he told Dr. Jennifer Powell that, "my shoulder was absolutely killing me and I was surprised the pain was still there after receiving the flu shot at her office." *Id.* Petitioner explained that his pain had been "continuous" from the time he received the flu shot until mid-January 2017. *Id.* at 18. He stated that Dr. Powell "put me on a higher dose regimen of Advil, ibuprofen," and he was given a muscle relaxer as well. *Id.* at 18. Further, Dr. Powell gave him a referral to Boston Sports Medicine. *Id.*

Later that week, petitioner had an appointment with Physician's Assistant, Mr. Brian Petrone at Boston Sports Medicine. Tr. 19. Petitioner stated that he had told Mr. Petrone that his left shoulder pain "began immediately following the flu shot," and that he meant to relay that he had "always had pain with decreased motion since receiving the flu shot. I was very clear about that." *Id.* at 22. Petitioner was recommended to start physical therapy and undergo an MRI of the left shoulder. *Id*. Petitioner testified that he returned to Boston Sports Medicine to review the

MRI. *Id*. Petitioner explained that after the MRI of his left shoulder, he had appointments at Boston Sports Medicine for both his knee and shoulder. *Id.* at 23.

When petitioner was asked about an appointment from January 2014, which noted a "history of radiculopathy," petitioner responded that he did not "know what that means," and that he did not believe he had "radiating nerve sensations to any of his extremities around 2014." Tr. 29. Further, petitioner clarified that he experienced knee pain in 2015, but initially sought care in 2016. *Id.* Petitioner was also asked if he ever had seen Dr. Daniel Ward, an orthopedic surgeon that petitioner was referred to by Dr. Commito and petitioner responded that he did not recall if he had met with Dr. Ward. *Id.*

Petitioner testified that sometime in 2015 he was having pain in his knee, which is what originally brought him to the September 2016 appointment where the flu shot was administered. Tr. 23. During cross-examination petitioner testified that he was prescribed physical therapy for his knee in October 2016 until December 20, 2016, when he was discharged. Tr. 32. He was also asked why he never mentioned his shoulder pain to the physical therapist. *Id*. Petitioner testified that he "did mention it to them, but they were just primarily focused on the knee." *Id*. During cross-examination and by the Court petitioner was asked about the specific exercises completed during this time period of physical therapy, and he explained that it primarily "focused on leg stretches." *Id*. at 34.

Petitioner testified that the physical therapy was largely unsuccessful, later requiring an arthroscopic surgery to fix a meniscus tear in March 2017. *Id*. at 24. He explained that the main focus in the later winter and spring of 2017 was his knee. *Id*. at 25. During cross-examination, respondent pointed to post-surgery physical therapy record from March 9, 2017, at which time petitioner told the physical therapist about his shoulder pain. Tr. 32. Petitioner was asked if shoveling the snow bothered his shoulder. *Id.* Petitioner stated, "It did. It absolutely did. I also have a snowblower with a clutch, and I could engage the clutch to push the snowblower. It would almost self-drive itself, but occasionally you need to shovel to get areas where I couldn't get in with the snowblower." *Id.* Respondent's counsel questioned whether shoveling snow would be a "bad idea because of [the] shoulder pain," and petitioner responded, "…I know it was a bad idea to do a lot of silly things, you know, trying to-because I have got such a physically fit mentality that I continually want to challenge myself to do the things that I used to do, but it's always met with a lot of pain." Tr. 39.

Petitioner was asked if the physical therapy for his post-surgery knee and for his shoulder were by the same medical practice group. Tr. 26. Petitioner testified that they were the same practice, but different locations, the practice for his shoulder was closer to his home. *Id*. When asked for clarification from the court regarding his physical therapy sessions, petitioner responded that during the post-surgery physical therapy appointments the physical therapist noticed that he was favoring his shoulder, and therefore he had a few sessions where he worked on his shoulder as well. *Id*. at 27.

Petitioner explained that his shoulder never felt better while attending physical therapy for his shoulder, and to the day of the hearing he "can still feel the pain in the shoulder," and feels "like there's a bee stinger" in his shoulder. *Id*.

2. Testimony of Cheryl Galante, Petitioner's Wife

Mrs. Galante, petitioner's wife, has known her husband for 45 years and has been married to him for 35 years. Tr. 41. She testified that she remembers the day he got the vaccination because she urged him to go to the doctor to address his ongoing knee pain. *Id*. She stated that nothing was out of the ordinary directly after the appointment, but that he was unable to sleep well, "he was moving around a lot, getting up and just not sleeping." *Id*. at 42. She stated that she asked her husband why he wasn't sleeping well and he responded that his arm was bothering him following the flu shot. *Id*. She stated that he mentioned the pain in his shoulder to her about a week following the flu vaccination. *Id*. at 43.

Mrs. Galante stated that she remembered looking at her husband's shoulder and she observed it was "red, raised, and like hard in the middle." Tr. 43. She described the point on the shoulder as "higher up," and that it looked "like a circle, and it was raised up, and it was red around it…and it did feel a little hard like in the center." *Id*. Further, she stated the mark was "a little bigger than a quarter." *Id*. at 44. During cross-examination, petitioner was asked why she did not reference the redness and other symptoms in her 2019 affidavit. *Id*. at 47. She explained that it was a long time ago and she didn't know why she didn't write this in her affidavit. *Id*. at 47-48. The Court asked Mrs. Galante, "when did the notion that this felt like a bee sting first come up?" *Id*. at 48. She testified that when she touched his shoulder, "you could feel like it was something hard…it felt like when you get stung by a bee." *Id*. She also stated this was in the early months after the flu vaccine. *Id*.

She testified that prior to the September 2016 flu vaccination he never complained of pain and injuries in his left shoulder. *Id*. Following the vaccination, Mrs. Galante testified that his "range of motion stopped [and] he couldn't lift it up." *Id*. During the hearing the Court verbalized what Mrs. Galante was demonstrating with her own shoulder, to demonstrate that her husband could "raise his arm to about shoulder level but not higher." *Id*. at 45.

Mrs. Galante testified that as a result of his shoulder pain he "couldn't really do a lot…shoveling was hard [and] he would ask me not to buy anything that needed to be put together." Tr. 45. She stated that she saw her husband use a lot of at-home remedies such as Advil, and ice. *Id*. By January, she stated that she pushed him to go to the doctor because something was wrong with his left shoulder. *Id*. at 46. When asked why she pushed him to go, she testified, "because he doesn't go to the doctor and he just sucks it up. I just knew something was wrong…and he finally made the appointment." *Id*.

Mrs. Galante testified that her husband is "still in a lot of pain. I can see it. You can't even touch him over there. He does still take a lot of Advil. He does have sleepless nights. It's still painful for him, but he just goes through the pain and just carries on." Tr. 46. She explained that her husband's shoulder injury has impacted the family, as he "can't do a lot of things he would normally do for us," and "he's not doing the things that he would normally do since this has happened to him." *Id*. at 46-47.

3. Testimony of Melissa Dell'Orfano, Vaccine Administrator

Ms. Melissa Dell'Orfano, was the vaccine administrator at Hallmark Health Medical Associates ("Hallmark Health") who administered the injection to Mr. Galante. Tr. 49-50, 62-63. She testified that her job title is a Medical Assistant, and she obtained a certificate to become a medical assistant. *Id*. at 50. She testified that she attended the Bryman Institute and then attended Salter, both educational institutions in the Boston area and the total schooling took a little over a year. *Id*. Ms. Dell'Orfano testified during her education she had to take tests throughout, and complete "180 hours of actual in-office training," over the course of two months in the Hallmark Health office. *Id*. at 51. Following the training, she began working at Hallmark Health full time in June 2015. *Id*. at 52.

Ms. Dell'Orfano described her normal day at the office, which included getting patients to their rooms, taking their vitals, administering vaccines intramuscularly, subcutaneously and less frequently intradermally, give medication, demonstrate how to use at home machines, draw blood, keep clinical areas and rooms clean, check patients in, schedule appointments, and triage patients on the phone. Tr. 53-54. She testified that she was trained to administer vaccines in school and during her in office training with Hallmark Health. *Id*. at 54. She testified that as part of her regular job duties she regularly administered "intramuscular, sub-Q…PPDs[8] that are just administered underneath the skin…[and] any other kind of medication injection." *Id*. Ms. Dell'Orfano stated that over the course of her career she has administered thousands of intramuscular vaccinations, and regularly administered subcutaneous vaccination, "but it's not as frequent as the [intramuscular]." *Id*. at 55. She estimated that she likely only used the intradermal injector about 50 times and it was only used in the 2016-2017 flu season. Tr 63. She agreed, that given that Mr. Galante received his flu vaccine on September 7, 2016, that that would have been early in the time that they were using the intradermal injector. *Id.*

Ms. Dell'Orfano testified that she was specifically trained on the administration of intradermal vaccination by a nurse on staff in late August or early September 2016. She stated that the staff "were kind of pushed to give this one more" at the start of the flu season in 2016. *Id*. at 55-57. This was the first time that they were given the intradermal injector for the flu vaccine. She testified that she practiced on a patch attached to the shoulder, and "you would press the button on the back and it would sort of inject into the patient's arm." *Id*. at 56. She stated it was a "very small needle," and added that "the company that gave us the vaccines came and made sure that we were doing it correctly." *Id*. at 57.

Ms. Dell'Orfano was then asked to walk through the process of intradermal vaccine administration, and she responded that "we were told to put three fingers from the top of your

[8] A PPD is a "purified protein derivative, a solution injected under the skin. PPD is a protein that comes from the bacteria that causes TB. It is administered by injecting a small amount of purified protein from the mycobacterium tuberculosis complex. If it is suspected that a person has been exposed to tuberculosis it is usually administered intradermally in the forearm to test for the presence of the bacteria. A different type of needle is used than that in question in this case. Tuberculosis (TB) Test, CLEVELAND CLINIC, My.ClevelandClinic.org/health/diagnostics/22751-tuberculosis-tb-test (last visited Sept. 21, 2022).

shoulder down…that's where you would inject the [intramuscular]." *Id*. at 57-58. Ms. Dell'Orfano further testified that the location of administration for the intradermal and intramuscular vaccines is the same. *Id*. at 58-59. She testified that the main difference between an intramuscular and an intradermal vaccination is in an intramuscular "you have the syringe where you push it in, the medication goes in," with the intradermal "you just sort of tap the back and it clicks it in." *Id*. at 58. She testified that "you basically put it to the skin where you are going to inject it…and you would just click and it injects the medication into the patient." *Id*. She testified that pressure had to be added "because you have to hear that click to know that the medication actually went into the patient. And it sort of retracted the needle into the syringe." *Id*. at 60. Ms. Dell'Orfano demonstrated her technique for using the intradermal injector. She demonstrated that she placed the injector against the skin and pressed down with her thumb *Id*. Even though the instructions specifically said to grip the injector between the thumb and second finger and press lightly with the index finger. Resp. Ex. C-2 at 4.

During cross-examination, Ms. Dell'Orfano was asked to look at a picture of the intradermal vaccine apparatus. Tr. 64. She testified that there is a circle around the needle, and when you administer the vaccine that circle sits flush against the skin, and regardless of how much pressure is put on, there is no way to control how far the needly goes in or does not go into the skin. *Id*. at 64-65.

In response to a question regarding the creation of vaccine administration records at Hallmark Health, petitioner testified that doctors would put orders in the system for a flu vaccine, and Ms. Dell'Orfano would ask each patient if they would prefer the intradermal or intramuscular vaccine, she would then go to the fridge to get the vaccine, print the vaccine administration form, place the sticker off the vaccine and onto the consent form, and circle L or R to indicate which arm it was administered in. Tr. 60-61. She explained that she would then bring everything to another medical assistant or a nurse to cross-check everything, then sign off on that, go back into the room with the patient, have them sign the consent, ask a series of questions regarding allergies, and administer the vaccine. *Id*. at 61. She confirmed that she administered the flu vaccine to petitioner, based on the medical records that indicate "Given By: Dellme," a user ID created in the medical record system to identify her. *Id*. at 62.

She testified that during the 2016 to 2017 flu season she administered approximately 50 intradermal flu vaccines. *Id*. at 64. In response to a question from the Court regarding the date of vaccination on September 7, 2016, and Mrs. Dell'Orfano responded it was early in the year the office was using intradermal vaccines. *Id*.

III. Expert Opinions Regarding Intradermal Vaccine Causation

a. Petitioner's Experts' Opinions on Causation

1. Dr. M. Eric Gershwin's opinion

Petitioner submitted two expert reports by Dr. Eric Gershwin, an immunologist, to provide an opinion on vaccine causation. Pet. Ex. 10 (ECF No. 20); Pet. Ex. 24 (ECF No. 29). Dr. Gershwin reviewed petitioner's medical records and a scheduling order I issued questioning

the immune response in intradermal vaccines. Pet. Ex. 10 at 1. Dr. Gershwin opined that "there is evidence that intradermal vaccines can cause a systemic inflammatory response." *Id*.

In his first report, Dr. Gershwin stated that "intradermal injections are actually difficult and often lead to local bleeding, and not uncommonly, become subcutaneous injections." Pet. Ex. 10 at 1. He drew a comparison between systemic reactions in allergy skin tests, to intradermal vaccines as seen in this case. *Id*. Referencing the *Rosenbaum et. al.* article, Dr. Gershwin stated that "the authors documented that even though the injection was intradermal, there was evidence of systemic inflammation confirmed by molecular signatures, including the upregulation of IL-6 and TNF and acute phase response signaling." Pet. Ex. 10 at 2.[9] The authors of the study sought to better understand early systemic changes, including changes at the site of injection which are responsible for a protective immune response generated by the intradermal injection of a modified Ankara vaccine. Pet. Ex. 19, Tab E. The authors explained that "the skin is an ideal target for vaccine injection due to the diversity of resident and recruited immune cells, including macrophages, Langerhans cells, and several subsets of dermal dendritic cells. *Id*. at 2. Further, they noted "a strong early local and systemic inflammatory response that peaked at 24 hours post-vaccination, which was then progressively replaced by an adaptive response." *Id*.

Dr. Gershwin testified specifically as to "whether the intradermal injection could produce a systemic reaction…not to provide any opinion whatsoever regarding the etiology of the shoulder complaints." Tr. 67. Further, he stated that vaccines must elicit a systemic reaction "otherwise you wouldn't have an immune response and your vaccine wouldn't work." *Id*. at 68. Dr. Gershwin stated that an intradermal vaccination is ideal, "because the skin is the second largest immune organ in the body, and it's an ideal way to present antigen and elicit an immune - protective response." *Id*.

When asked if petitioner had a systemic reaction to the intradermal vaccination, Dr. Gershwin opined that he did not, and testified that "it sounded so immediate that it sounds more of acute discomfort than an immunological reaction." Tr. 69. Further Dr. Gershwin stated the response was "certainly acute and local," and he didn't "believe the immediate reaction he's describing is either immune or inflammatory. It may well have gone on to be inflammatory, but in terms of what I have done, I don't believe there was systemic [reaction] and I don't believe acutely it was immunological either." *Id*. at 69-70.

The Court asked Dr. Gershwin about the immunological ability of the intradermal vaccine to cause the type of pain that was described by petitioner. Tr. 70-71. Dr. Gershwin testified that he cannot explain immunologically why petitioner experienced acute pain, "in the absence of swelling of lymph nodes, which can certainly happen, it won't happen as quickly as he described it." *Id*. at 71. Additionally, the Court asked about the redness, swelling, and hardness at the site of vaccination and if Dr. Gershwin could explain what was causing that pain. *Id*. at 72. Dr. Gershwin stated that without an early MRI he "couldn't come up with an immunological explanation," for Mr. Galante's early onset pain. *Id*. He testified that it was

[9] Rosenbaum, et. al., *Molecular and Cellular Dynamics in the Skin, the Lymph Nodes, and the Blood of the Immune Response to Intradermal Injection of Modified Vaccinia Ankara Vaccine*, 9 Frontiers of Immunology 87 (2018). [Pet. Ex. 9, Tab E].

possible Mr. Galante's threshold was lower than someone else, but he could not "come up with an immunological explanation." *Id*.

In his supplemental expert report, Dr. Gershwin stated that his opinion on causation "is not based on the depth of the needle and I agree completely that an intradermal injection will not directly injure the tendons." Pet. Ex. 24 at 1. Dr. Gershwin wrote that "vaccination leads to firstly a local immune response within the nearby lymphatics, which will then traffic through the interstitium through other lymph nodes. It is also well known that reactions can lead to significant swelling and this is part of the systemic reaction. In other words, the response to vaccination includes an inflammatory response." *Id.* at 2. He stated that, "This inflammatory response, like any other mechanical event, can obstruct or impinge on adjacent tissues, including the bursa, the tendon, and the local nerves." *Id.* He wrote that his opinion "regarding lymphatics is well documented in the literature," and referenced the *Swartz et al.*, review article to provide an overview of the lymphatic system and its role in immune responses to antigens. *Id.* at 2. The *Swartz* article explains "Dendritic cells ("DCs") are the most potent and important antigen-presenting cells ("APCs") because of their capacity to take up and process antigens and present them to naive T cells. ….dendritic cells are physically positioned to take up antigen from peripheral tissues and carry them to the lymph node so that circulating T cells only need to traffic through the lymph nodes to interact with all APCs." Pet. Ex. 25 at 1.[10] Further, *Swartz* states that "The lymphatic vessels are thus critical for transporting activated dendritic cells from their periphery to the lymph node. They constantly deliver a representative sampling of interstitial fluid to the lymph node, allowing immature dendritic cells and macrophages there to screen potential antigens and also to carry inflammatory signals from the tissue to the lymph node faster than peripheral, migrating dendritic cells can, possibly preparing the lymph node for the need to increase surveillance there in preparation for a pending immune response." *Id.* The authors explain that "vaccine strategies have targeted peripheral dendritic cells by delivering antigen to peripheral dendritic cells in the skin….which in turn migrate to and enter the lymphatic capillaries, and subsequently migrate to the lymph nodes to present antigen and co-stimulatory molecules to T-cells." This process stimulates the adaptive immune system. Dr. Gershwin concluded that the petitioner suffered a shoulder injury caused by his inflammatory reaction to the intradermal flu vaccine. Pet. Ex. 24 at 2.

2. Dr. G. Russell Huffman's opinion

Petitioner's orthopedic expert, Dr. G. Russell Huffman, opined that petitioner's presentation is consistent with rotator cuff inflammation or bursitis in the subacromial space, injuries consistent with a SIRVA injury. Pet. Ex. 11; Pet. Ex. 26. He further testified that vaccine deposited into the adipose tissue beneath the dermis would cause pain and was likely to have caused petitioner's pain. Tr 131.

Dr. Huffman testified that the dermal layer can be "as thin as 3 mm." Tr. 107. He acknowledged that the length of the intradermal vaccine is 1.5 mm, or a "fixed length." Tr. 107-08, 121. However, he argued, "Should one push with force….You could easily get to a depth of close to a centimeter with this needle." Tr. 107. Dr. Huffman stated, "the dermis is only so

[10] Swartz, M., et al., *Lymphatic drainage function and its immunological implications: from dendritic cell homing to vaccine design*, 20 Seminar in Immunol. 147-156 (2008). [Pet. Ex. 25].

thick, but we know that skin is compliant because it moves around our joints….so with force enough to dispose the needle or retract the needle, I suspect that this went in quite a ways deeper than it was intended, possibly more than a centimeter or more." Tr. 107. After he reviewed the transcript from the vaccine administrator, he stated "clearly the device was not properly used and too much force was used to administer…the microliters of volume that was in" the vaccination at issue. *Id*. at 8. Dr. Huffman analogized the intradermal needle to a thumbtack. Tr. 110. Dr. Huffman testified that "if I were to take a thumbtack, being about a centimeter in length, and push it into the side of someone's shoulder, it would stop at the depth of a centimeter." *Id.* He argued that "if I push with more force, the investing skin and soft tissue would also indent and the needle would go further and further as I push harder and harder." *Id.* Dr. Huffman stated, "That's not to say that the plastic portion of the piece of the thumbtack is going to penetrate the skin, but the needle depth will be determinant on the amount of force used to imprint the thumbtack in that region." *Id.* Dr. Huffman also observed that the Fluzone intradermal packet insert itself indicates that local adverse reactions are more common with the intradermal vaccination than the intramuscular injection. Tr. 124; *see also* Resp. Ex. C, Tab 2. He stated, "specifically with this quadrivalent vaccine, the local adverse reactivity was 76 percent, which is interesting." Tr. 124. He stated that "induration, swelling, itching, and even bruising was 50 percent or higher in a lot of cases." *Id.* Dr. Huffman was asked if he was aware of any medical literature around the risk of overpenetration with the Fluzone Intradermal apparatus, Dr. Huffman responded, "No, but I think that's why there was caution to keep the needle short and to be very explicit in the instructions." Tr. 117.

Dr. Huffman opined that petitioner had both a "local response" and a "regional reaction" Tr. 112. He described the local reaction to be evidenced by the hardened area that persisted for weeks near the injection site. *Id.* Dr. Huffman testified that "there's an early inflammatory response that's expected and hoped for, but also there could be a regional immunologic response as well, including lymphatic drainage." Tr. 112. Dr. Huffman opined that for a SIRVA and a local reaction, the needle does not need to go directly into the bursa, but "can have a response adjacent to that area and still have an effect." Tr. 114. Dr. Huffman opined that "if the vaccine is placed in proximity, not necessarily in directly, into a space like the bursa, that is a proinflammatory space with synovioctye-like cells that love to regulate the vascularity of itself in response to trauma." Tr. 113. He stated that "the blood supply is very rich there. Macrophages and other cells can be recruited very quickly, and we see that with the calcific tendinopathy, with contusions adjacent to bursal areas can create bursitis or inflammatory response in the bursa." *Id.* Dr. Huffman stated, "…it's very plausible that…were there [be] an injection adjacent to the bursa with an inflammatory response that the bursa would become involved as well in the regional response." Tr. 113. On cross-examination, Dr. Huffman explained further that inflammation could spread to the bursa from adjacent areas. Tr. 122. He stated, "…we will see contusions to the deltoid and adjacent areas or if we do surgery or have trauma to bones and structures near the bursa, [the bursa] can be involved in an inflammatory process which can entail pain and/or stiffness." *Id.*

Dr. Huffman stated that petitioner's symptoms were consistent with rotator cuff inflammation or bursitis in the subacromial space. Tr. 115; Pet. Ex. 11 at 5. Dr. Huffman stated that petitioner's MRI findings of a glenoid labrum tear and degeneration within the acromioclavicular joint "have been observed to be typical findings even in asymptomatic

individuals undergoing MRI of the shoulder and are unrelated to the symptoms described by Dr. Gill. Pet. Ex. 11 at 5. However, all the symptoms that petitioner reported to his doctor post-vaccination, including limited range of motion and pain, were consistent with rotator cuff inflammation or bursitis and "there was no clear documentation that those [other MRI findings] were actually bothering [the petitioner]." Tr. 115. When asked if he agreed that there was no evidence of bursitis on the MRI, he stated, "I think there was a trace amount of fluid that I discussed. You know, scar tissue inflammation along the bursa is not always seen and there are plenty of patients where I will go at the time of surgery and notice a lot of adhesion scar tissue that is not visible on MRI. It's a clinical diagnosis. Not a radiologic diagnosis." *Id.* at 123.

Dr. Huffman opined that the proposed mechanisms outlined in the papers "range from direct injection into the bursa with a resultant inflammatory response, to injury from the needle, and a regional immunogenic response." Pet. Ex. 11 at 5. Dr. Huffman opined that petitioner "exhibits symptoms identical to documented cases of shoulder injuries related to flu vaccine administration in the deltoid." *Id*. at 6. The *Cook* article explains that "the deltoid muscle of the upper arm is a site generally accepted for the injection of vaccines in children aged 12-18 months, older children and adults. Injection site reactions, such as pain, erythema, induration and swelling at the injection site are commonly recognized transient sequelae of intramuscular vaccination of the muscle in adults. Much less frequently, persistent dysfunction has been reported following injection of the subdeltoid/subacromial bursa, anterior branch of the axillary nerve and the radial nerve." Pet. Ex. 15 at 1.[11] *Cook* states that there are four different methods recommended for site selection for intramuscular injection of the deltoid muscle, but "all the injection site selection methods currently recommended have the potential to cause injury to the subdeltoid/subacromial bursa and/or the anterior branch of the axillary nerve within the arm in the neutral position." *Id.* at 3. Additionally, *Cook* opines that the complications from post-vaccination shoulder injuries are "presumably result from a lack of awareness of the anatomical position of these structures within and near the deltoid muscle." *Id.* at 1.

The *Bodor* article hypothesized shoulder pain and weakness following vaccination was because the vaccine was injected into the subdeltoid bursa, caused a periarticular inflammatory response, subacromial bursitis, bicpital tendonitis, and adhesive capsulitis." Pet. Ex. 14 at 2.[12] The authors found that the "skin to subdeltoid bursa distance" in their male patient was 0.6 cm. *Id.* at 2. The authors stated, "Given that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule." *Id*.

The *Okur* article examined MRI imaging results of four patients with shoulder pain following the flu vaccination. Pet. Ex. 18 at 1.[13] The authors found that small fluid within the subacromial/subdeltoid bursa was found in three of the four patients in the study, and that

[11] Ian F. Cook, *An evidence based protocol for the prevention of upper arm injury related to vaccine administration (UAIRVA),* 7 Human Vaccines 8, 845-848 (Aug. 2011). [Pet. Ex. 15].

[12] Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction*, Vaccine 25, 585-587 (2007). [Pet. Ex. 14].

[13] Gokcan Okur et. al., *Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination,* Skeletal Radiol. 43, 1325-1331 (2015) [Pet. Ex. 18].

"unintentional injection of vaccine antigen into subacromial/subdeltoid bursa can trigger an inflammatory reaction." *Id*. at 5. It should be noted that the MRIs in this study were performed at 10, 20, 24 and 30 days post injection. *Id.* In the fourth case reported about in *Okur,* the patient complained of severe pain localized at the injection site following the flu vaccination and he had a subjective decrease in range of motion due to pain. *Id.* at 3. The authors noted that the patient had a subcutaneous fat thickness of only 4.2 mm. *Id.* Additionally, the authors opined that "an improper angle of approach of the needle or increased needle length may result in bursal or cortical penetration, particularly in those with low BMI." *Id.* at 5. The *Okur* authors endorsed *Bodor's* theory that the vaccines triggered an inflammatory response by the antigenic or non-antigenic components of the vaccine in the shoulder structure, resulting in shoulder symptoms. *Id.* at 6.

During the hearing, the Court asked Dr. Huffman to opine on "the outcome if the needle was pressed through the intradermal space and was delivered into the adipose tissue." Tr. 127. Dr. Huffman stated that the adipose tissue is also a very vascular area," and if the needle is injected with force "that fluid will be pushed several millimeters deeper than the actual needle." Tr. 127. He further opined that the adipose tissue is innervated with pain fibers and that if the vaccine was delivered into the adipose tissue, as opposed to the intradermal space it could "potentially cause the type of pain that [petitioner] experienced." *Id*. at 128.

The Court asked Dr. Huffman whether the vaccine administered beneath the dermis but not all the way into the deltoid muscle could still cause pain, and he responded that "it was likely to have caused his pain." Tr. 131. The Court additionally asked if the pain "would cause limitation of his range of motion as experienced here," and Dr. Huffman opined that it would cause limitation secondary to pain as opposed to something like adhesive capsulitis. *Id*. Regarding whether petitioner's ongoing pain after five years was likely the result of the vaccination Dr. Huffman opined that "it sounds consistent with the pain he experienced shortly after the vaccination. So my opinion would be that it is." *Id*. at 132-133. Dr. Huffman clarified that his opinion, offered to a reasonable degree of medical certainty was that Mr. Galante's injury and pain was more likely than not caused by the intradermal injection. Tr. 129-130.

b. Respondent's Experts' Opinions Regarding Intradermal Vaccine Causation

1. Dr. Harry W. Schroeder's opinion

Respondent submitted one expert report by Dr. Schroeder, an immunologist, and he opined that petitioner suffered from degenerative changes in his shoulder that manifested with persistent pain and he did not believe the condition was either caused or even aggravated by the intradermal flu vaccine he received on September 7, 2016. Resp. Ex. C at 12. He stated that, "the cause of Mr. Galante's condition is more likely the sequelae of his previous avid pursuit of contact sports and engagements, and the only link between his disease and the vaccination is at best due to chance alone." *Id.*

Dr. Schroeder opined that he agrees with the diagnosis of degenerative changes of the AC joint, tendinosis without tear of the biceps long head and supraspinatus, tearing of the labrum, degeneration of the superior/posterosuperior labrum and possible tearing of the superior labrum

as visualized by a radiologist during his treatment course, and confirmed by Dr. Thomas Gill. Resp. Ex. C at 11. He also agreed with Drs. Huffman and Gershwin that vaccinations can have adverse consequences, however he did not believe that the flu vaccination was the cause of the left shoulder symptomatology in Mr. Galante. *Id.*

In his expert report he provided three reasons why the intradermal flu vaccine was not the cause of petitioner's left shoulder symptomatology. Resp. Ex. C at 11. First was that there was insufficient documentation of the temporal relationship between the administration of the vaccination and the onset of petitioner's left shoulder pain. *Id.* at 11. He notes that the first medical documentation of petitioner's left shoulder pain was on January 20, 2017, more than four months after vaccine administration.

Secondly, Dr. Schroeder opined that the Fluzone vaccine utilized "a microinjection system…to deliver the vaccine into the dermis," and it "is simply not long enough to enter the joint and deposit vaccine substance and thus his injury by definition cannot be attributed to SIRVA." *Id.* at 7, 11-12. He stated that the microinjection system, "employs a tiny hollow microneedle that penetrates 1.5 mm into skin from the outer skin surface to deliver a volume in the range of 100-200µl." *Id.* Dr. Schroeder posited that the vaccine would be delivered into the intradermal space and while he could understand a hypersensitivity reaction with local pain at the site of the injection occurring, he did not see how a patient could suffer shoulder pain and limitation of range of motion because of the local reaction to an intradermal injection. Tr 87-89.

Thirdly, Dr. Schroeder opined that the pain petitioner experienced in his right knee and left shoulder "appear to result from degenerative changes in his joints." *Id.* at 12. Dr. Schroeder referenced the *Possley* article, which explored musculoskeletal injuries sustained in modern army combat, in relation to petitioner's hobby of mixed martial arts. Resp. Ex. C, Tab 4.[14] Dr. Schroeder opined that the physical complaints in Mr. Galante's knee and shoulder are most likely related to the "sequelae of pursuit of his athletic hobbies," and that the onset of pain in proximity to the vaccination was merely a coincidence. Resp. Ex. C at 12; Tr. 86.

During the hearing, Dr. Schroeder stated that the likely mechanism for a SRIVA with an intramuscular vaccine, is the "needle, instead of going into the muscle, goes into the synovial space in the joint. And then [one] can deposit the vaccine material there, and that will elicit a local immune response that can lead to joint pain." Tr. 77. He explained that "you don't want to have it high enough where [the injection] would go into the joint." *Id.* He testified that the intradermal injection was designed "to avoid that possibility." *Id.* Dr. Schroeder cited to the picture from his expert report to describe the dimensions of the intradermal vaccine injector, which contains a needle that was 1.5 millimeters long. Tr. 78. He stated that the depth of the skin is 2 to 4 millimeters. *Id.* He opined, the "needle will not penetrate the skin and thus, in no way can enter in the joint space and cause the arthritis that's caused by your deposition of energetic material that could be caused by doing an intramuscular injection in the wrong place." *Id.*

[14] Daniel R. Possley & Anthony E. Johnson, *Muscoskeletal Injuries Sustained in Modern Army Combatives*, 60 Military Medicine 177, 60-63 (2012), [Resp. Ex. C Tab 4].

During cross-examination, Dr. Schroeder was asked to read from his expert report regarding the "adverse reactions to Fluzone Intradermal Quadrivalent vaccine." *See* Resp. Ex. C at 7; Tr. 79. He testified that his expert report acknowledged that "pain is a common injection site reaction," and that "redness or erythema is also a common injection site reaction," to the intradermal vaccine. Tr. 79-80; *see also* Resp. Ex. C. at 7. He also acknowledged that petitioner had testified that he experienced pain, redness, and swelling after receiving the intradermal vaccine and that these were all common side effects listed on the package insert. Tr. 80. However, he denied that "decreased range of motion" was a "common reaction to the vaccination." *Id.*

Dr. Schroeder was also asked if his opinion about vaccine causation in this case changed based on petitioner's testimony that his left shoulder pain began immediately after receiving the intradermal vaccine. Tr. 81. Dr. Schroeder replied that the "description that we have of the event is a new description that was not present in the information given to me before….The description that we had this morning from the plaintiff and his wife describing what happened locally…after the vaccination…was new to me." *Id.* However, he agreed with "Dr. Gershwin that the initial pain that [petitioner] suffered was likely not immunologic but an irritant." *Id.* at 82.

He stated that the hardness petitioner described after 48 hours and then the slow resolution of the hardness and redness "sounds very much like a Type IV hypersensitivity reaction." *Id.* Dr. Schroeder defined a Type IV hypersensitivity reaction to be a reaction that typically takes 24 to 48 hours to develop, and what you see is "local swelling, redness, and induration." Tr. 88. It's the type of reaction you elicit when you have a TB skin test, which is also done intradermally." *Id*. at 82. Dr. Schroeder stated:

> the immune system has T-cells that are specific to the antigen in question, and when you deposit the antigen within the skin, T-cells become attracted to the antigen. And the hardness is due to the accumulation of T-cells where they stick to the site of inflammation. It takes a while for T-cells to be engaged, about 24 to 48 hours. That's why the hardness and induration is most prominent at about 48 hours…It can take several days to even a few weeks for all the redness to go away.

Tr. 82-83. In his opinion, the redness and hardness petitioner experienced was "a completely local reaction." *Id.* at 83. The Court then asked Dr. Schroeder's opinion on why petitioner experienced "redness, swelling, and pain," immediately following the vaccine. *Id.* Dr. Schroeder responded, "[Petitioner] had a local reaction, which is actually in the list of side effects that you can have from the vaccine: erythema, redness, swelling and induration, hardness. So these are common local side effects from intradermal injections." *Id.* He continued, by stating, "…in some cases they are done on an irritant basis. In some cases they are done as a result of innate immune response. In some cases, there's a delay type hypersensitivity response due to the activity of T-cells. But they are localized. They don't involve the shoulder." *Id.* at 84-85.

The Court also asked Dr. Schroeder his opinion on how the initial pain and hard spot from the vaccination "persisted" so much that petitioner pursued physical therapy. Tr. 85. Dr.

Schroeder responded, "My interpretation of the data is that this is two separate issues. Issue number one is the local inflammation that occurred as a result of the injection with local pain at the site of injection. But….I can't think of a mechanism how that local pain and irritation would then extend into the joint itself." *Id.* at 86. Dr. Schroeder attributed the petitioner's decreased range of motion and decreased strength to "degenerative changes," as evidenced in the MRI and "can occur to anyone and certainly someone who is active as [petitioner] has been." *Id.* He went on to characterize it as a "coincidence that the pain in the shoulder is associated temporally with the injection that he received." *Id.*

The Court prompted Dr. Schroeder to "not think about the interior of the joint, but think about the pain reaction in the intradermal area," and asked if it is "possible that you can get persistent pain in the area, in the surface area of the shoulder that remains painful over a long period of time." Tr. 86. Dr. Schroeder testified that one way to evaluate patients for evidence of immune deficiency is to check for efficacy and ability of the patient to produce a Type IV hypersensitivity reaction, in which patients usually develop "the local pain and irritation that [petitioner] described." *Id*. at 87. Dr. Schroeder additionally testified that "it sounds again a bit more intense than what we would see with most patients, but we have had patients that weeks after they have had the intradermal injection can point to the site at which it occurred and still feel some evidence of local discomfort of the skin at that site." *Id*.

The Court asked if it was possible that petitioner developed impairment in his range of motion because of pain protective behavior, and Dr. Schroeder responded that he cannot see a correlation, but he is an immunologist, not orthopedist or neurologist. *Id*. at 88. The Court also asked a question regarding operator error with overpressure with the vaccination in question. He acknowledged that none of the studies he cited accounted for operator error or over pressure in administering the vaccine, but he said the whole intent of the intradermal vaccination is that its "supposed to be less sensitive to operator error." *Id*. at 90-91.

2. Dr. Paul J. Cagle's opinion

Respondent submitted on expert report by Dr. Cagle, an orthopedic surgeon, in which he opined that the timing, mechanism, and injury in petitioner's case has not been established to connect the vaccination event and the onset of shoulder pain. Resp. Ex. A at 2. Dr. Cagle opined that beyond petitioner's own reporting, there is no medical record that established a "48-hour link between the vaccination event and the onset of shoulder pain." *Id*. Dr. Cagle then responded to Dr. Huffman's suggestion that the pain is linked to the vaccination, and responded that there is not a "viable theory nor an exact diagnosis for what was injured," and "no description of how an intradermal injection was able to penetrate all the way to the bursal area or the biceps area." *Id*. at 2-3. Dr. Cagle also responded to Dr. Gershwin's theory regarding a systemic response following the flu vaccination that can cause a local shoulder response. *Id*. Dr. Cagle concluded that there is no "literature presented which links a systemic event to a local joint pain event." *Id*.

Regarding the MRI, Dr. Cagle opined that petitioner's case is "in stark contradiction to the published SIRVA literature," and the MRI performed on January 27, 2017 "demonstrated no significant joint effusion or bursitis but there is a notation of chronic shoulder conditions consisting of labral degeneration, mild biceps tendinosis and minimal rotator cuff (supraspinatus)

tendinosis." Resp. Ex. A at 3; Pet. Ex. 3 at 3-4. Dr. Cagle testified that in SIRVA cases fluid in the area of the bursa is a common finding on MRI. Tr 160. He testified that the MRI findings in this case did not provide objective support for a localized inflammation in the bursa. *Id*. at 161. During cross-examination, Dr. Cagle testified that "according to documented literature on SIRVA" the fact that the MRI was not done until four and a half months after the vaccination, it is still an appropriate time frame to demonstrate bursal fluid.[15] Tr. 162. He argued that in petitioner's case the MRI report said no significant amount of fluid seen, so in his opinion that meant that there wasn't even a small or a trace amount seen at this point in time." *Id*.

Regarding how the intradermal vaccine caused a deep inflammatory localized shoulder reaction, Dr. Cagle opined that "it would require a needle over 1 inch in length to penetrate the bursa of a person in [petitioner's] weight range." Id. at 4. Dr. Cagle cited to a study by *Poland*, which found that a one-inch needle was determined to be "safe and recommended for patients weighing between 60 and 90 kg." *Id*.; Resp. Ex. A, Tab 11.[16] He testified that the likely mechanism for a SIRVA injury is overpenetration, "that by placing the injection with a long needle, [or using]a bad technique or a combination of both, that you over penetrate the deltoid muscle, causing either a penetrating sharp injury and/or an immune response to the vaccine contents and/or the adjuvant." Tr. 139. Dr. Cagle testified that in this case, the administrator used 1.5 millimeter needle, and "that would not have been capable of penetrating through the skin, subcutaneous tissue and muscle." *Id*. at 140. During cross-examination, Dr. Cagle testified that the layer of the dermis can be anywhere from 1.5 to 4 millimeter. Tr. 157.

In response to Dr. Huffman's testimony analogizing a thumbtack to the intradermal vaccine, Dr. Cagle did not "disagree with him that the thumbtack has the capacity to penetrate one centimeter into the skin because the typical metal shank length of a thumbtack is 1.2 centimeters." *Id*. at 141. But he clarified that he did *not* think it was possible for a "1.5 millimeter needle to press through those layers of tissues," because "the muscle, the adipose tissue layer and the bursa would all somehow have to be compressed down to less than 1.5 millimeters, which seems virtually impossible." Tr. 141-42.

Dr. Cagle agreed with Dr. Huffman, that "the findings on the MRI are findings that can be chronic degenerative changes that can be incidentally found on MRI findings of the shoulder." Tr. 145. Dr. Cagle testified that multiple studies in the SIRVA literature demonstrate "increased fluid signal in the bursa," and in this case petitioner did not have increased fluid signal. *Id*. Dr. Cagle opined that the MRI findings of "mild biceps long head and minimal supraspinatus tendinosis without discrete tearing," indicate "indeterminate age-related change…nothing specific about this finding." *Id*. at 146. Dr. Cagle testified that petitioner "was not diagnosed with adhesive capsulitis. Tr. 173.

In response to Dr. Huffman's testimony that the vaccination caused a tendinopathy in this case, Dr. Cagle testified that "I am unaware of any scientific connection between skin irritation

[15] Dr. Cagle did not make specific references to an article for the proposition that fluid in the area of the bursa would most likely be present on an MRI taken over four months post vaccination.

[16] Gregory A. Poland, et. al., *Determination of Deltoid Fat Pad Thickness: Implications for Needle Length in Adult Immunization*, 277 JAMA 21, 1709-1711 (1997). [Resp. Ex. A Tab 11].

and rotator cuff tendinopathy. I don't know how those two are connected, how it would skip the deltoid or the bursal layer or how it would individually choose the rotator cuff tendon." Id. at 147-148. When Dr. Cagle was asked if he knew of any evidence in the record of any injury that could have caused petitioner's shoulder symptoms, he replied that he did not. Tr. 149. Dr. Cagle stated that he "would not consider something that caused a 1.5 mm depth of penetration to the skin to be something of a significant injury or even something that [he] would classify in that category." *Id.* Additionally, he testified that there is no evidence that the vaccination in this case caused damages to adipose tissue which resulted in sustained injury that lasted at least six months. *Id*

During cross-examination, Dr. Cagle was asked about the proper administration of the intradermal vaccination, specifically that Ms. Dell'Orfano (the vaccine administration) testified that she used her thumb instead of her index finger. Tr. 150-151. Dr. Cagle agreed that the administration technique of Ms. Dell'Orfano was inconsistent with what was seen in the Fluzone administration packet. Tr. 151; Pet. Ex. 29 at 3. Further, he agreed that Ms. Dell'Orfano "activated the shield," by "pushing with her thumb until she heard the click." *Id*. at 152. Dr. Cagle testified that "it's highly unlikely that [the vaccine] penetrated deep to the skin given the body habitus of the reported individual and the medical record as well as the length of the needle." Tr. 158.

IV. Finding of Fact

Before reaching the question of vaccine causation, I must resolve the factual issue of onset. Petitioner alleges that he experienced pain within 48 hours of the intradermal vaccination. Respondent asserts that the medical records do not establish that petitioner's pain began within 48 hours of vaccination because he did not seek medical care for his left shoulder pain and dysfunction for four and half months post-vaccination. Resp. Post-Hearing Brief at 7, n. 2.

a. Legal Authority for Finding of fact

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. 42 U.S.C. § 300aa-11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." 42 U.S.C. § 300aa-13(b)(1). The undersigned must weigh the submitted evidence and the testimony of the parties' offered experts and rule in petitioners' favor when the evidence weighs in their favor. *See Moberly,* 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence"); *Althen*, 418 F.3d at 1280 ("close calls" are resolved in petitioner's favor).

The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See, e.g. Burns v. Sec'y of Health & Human*

Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). Specifically, "[t]he special master or court may find the first symptom or manifestation of onset of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." 42 U.S.C. § 300aa-13(b)(2). If the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19-20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

However, there is no presumption that medical records are complete as to all of a patient's conditions, as the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions.". *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). Afterall, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs*., No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). And, importantly, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991) (quoting the decision below), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992). The *Murphy* Court also observed that "[i]f a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account." *Id.*

Although witness testimony may be offered to overcome the weight afforded to contemporaneous medical records, it must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the Special Master must consider the credibility of the individual offering the testimony. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health and Human Servs.,* 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence there must be evidence that this decision was the result of rational determination. *Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993). The Special Master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y Health & Human Servs.,* 110 Fed. Cl. 184, 204 (2013) (citing § 12(d)(3); Vaccine Rule 8), *aff'd,* 746 F.3d 1334 (Fed. Cir 2014); *see also Burns,* 3 F.3d at 417.

b. Finding of Fact

1. Parties' arguments regarding onset

The petitioner claims that he suffered significant pain almost immediately after he received the flu injection on September 7, 2016, that the pain was caused by the injection and that that pain persisted for many months up to and including the time of the hearing. *See* Pet. Brief; Tr. 9-10, 27.

Respondent argues that there is insufficient evidence as to when the petitioner's pain began because petitioner did not seek medical treatment for four months after vaccination and

further argues that petitioner has not established that the appropriate temporal relationship between vaccination and the onset of his shoulder pain is 48-hours. Resp. Brief at 7, 16.

Respondent stated that petitioner first complained of left shoulder pain on January 20, 2017, four months and thirteen days after the vaccination. *Id*. at 3; *see also* Resp. Ex. C at 6. Respondent's expert, Dr. Schroeder, implied that petitioner's decision not to seek treatment for his left shoulder pain, while at the same time seeking treatment for right knee pain is contradictory of petitioner's statements that "it was not in my nature to complain about pain." Resp. Ex. C at 6. Dr. Schroeder stated, "A viable rationale for why it [was] acceptable to admit to pain in the right knee and accept therapy while it is not acceptable to admit to pain in the left shoulder and accept therapy at the same time has not been offered." *Id.* at 11.

In petitioner's reply, he argued that his symptoms occurred within the appropriate period after the administration of the influenza vaccination. Pet. Reply at 6. He reiterated that his left his shoulder pain began the same date as the influenza vaccination. *Id.*

2. Discussion and conclusion regarding the onset of petitioner's left shoulder pain and dysfunction

Petitioner has demonstrated by preponderant evidence that his left shoulder symptoms began within forty-eight hours of receiving the intradermal flu vaccine on September 7, 2016. More specifically, petitioner provided preponderant evidence that soreness leading to pain began on the same day as the vaccination.[17]

The testimony from the petitioner and his wife demonstrated that petitioner experienced soreness the same day he received the vaccine and that the lump that formed on his shoulder was there for "three weeks, a month or so following the vaccination. Maybe a month and a half," and the soreness leading to pain led to difficulties moving his left shoulder. Tr. 9-13. Petitioner testified credibly that his left shoulder felt sore and was painful after he received the intradermal flu vaccine. Tr. 9. Petitioner described the pain "like getting stung by a large bee, and it felt like the stinger was still in my arm." Tr. 9. Petitioner testified that his pain started directly following the September 7, 2016, vaccination and that the pain was "localized to that immediate area where I received the shot." Tr. 9-10. He testified that the vaccine administrator was standing above him while he was seated, and the intradermal flu vaccination was administered "kind of high, mid to back," close to the acromion bone. Tr. 8.

Petitioner described the pain on the day of the vaccination at a 9 out of 10 on the pain scale, and that he was unable to sleep that night due to the "stinging" in his arm. Tr. 9-10. He testified that he took Advil and iced his shoulder when he returned home. Tr. 10. In petitioner's affidavit he averred that "several days passed and the pain from the needle 'shot' did not diminish." Pet. Ex. 6 at ¶, Pet. Ex. 7 at ¶ 4. He also testified that "the pain persisted…[and] lasted for over a month." T. 11-12. Petitioner testified that he had difficulty moving his shoulder "immediately following the shot," and explained he still has "difficulty only because it causes

[17] This section only provides a finding of fact for when petitioner's left shoulder pain began. A discussion of the appropriate proximal temporal relationship between the intradermal vaccine and alleged injury is found in *Althen* prong three.

pain." Tr. 13. He testified that in mid-January 2017, at his wife's urging, he visited Dr. Powell at Hallmark Health Medical and described his pain level while relating it back to the vaccine at issue. Tr. 17; Pet. Ex. 1 at 14-17.

Petitioner's testimony was corroborated by the testimony of Mrs. Cheryl Galante, his wife of 35 years, that his shoulder pain began the same day he received the intradermal flu vaccination which she noticed because of his inability to sleep at night. Tr. 42. Mrs. Galante testified that the day petitioner received the vaccine, he did not sleep well, and approximately one week later "he finally said, you know, the flu shot I got, my arm's been bothering me, so I think that's why I'm restless." Tr. 42-43. She also confirmed the redness on petitioner's left shoulder and observed that his shoulder was "red, raised and like hard in the middle." Tr. 43. Mrs. Galante explained that petitioner is not the type of person to complain about pain, and he never had any injuries to his left shoulder prior to September 2016. Tr. 44. She stated that following the vaccination "his range of motion stopped…he couldn't lift it up." *Id.* Mrs. Galante stated that petitioner used at-home remedies to treat his pain with "a lot of Advil," and she would "see him ice it now and then." Tr. 45. She also explained that she pushed petitioner to go to the doctor in January 2017 because "something [was] wrong," and "because he doesn't go to the doctor and he just sucks it up." Tr. 45-46.

The testimony by the witnesses is consistent with the medical records, in which petitioner consistently related the onset of his shoulder pain and dysfunction to the vaccination on September 7, 2016. On January 20, 2017, petitioner presented to Dr. Jennifer Powell at Hallmark Health Medical Associates for an "acute visit" for "pain in flu shot area," which "occurred after having had a flu shot in September, ongoing for the past four months." Pet. Ex. 1 at 14. Specifically, the note states, "having problems with range of motion, issues of raising his arm in flexion." *Id*. at 15. Then on January 27, 2017, when petitioner was seen by Brian Petrone, PA-C at Boston Sports Medicine, the note states that petitioner is being seen for "lateral shoulder pain after the flu shot." Pet. Ex. 2 at 6. The appointment note also states that petitioner reported that "he has always had mild pain to the shoulder with [decreased range of motion] and [decreased] strength." He remains with persistent pain. The general pain and range of motion has not improved. He has difficulty with range of motion and grabbing things above male's shoulder area. *Id*. The same day he underwent an MRI of the left shoulder. On physical exam his forward flexion was limited to 100 degrees in flexion and abduction actively and 130 degrees passively. Muscle strength was 3/5. Pet. Ex. 2 at 6. Petitioner testified that he had never presented to any provider for pain in his left shoulder at any time prior to the January 20, appointment with Dr. Powell. Tr. 20-21. Petitioner returned to Boston Sports Medicine on February 3, 2017, and Dr. Gill noted in part "he also had a shoulder MR last Friday for left shoulder pain which may be related to a flu shot in 9/16." Pet. Ex. 2 at 5. On March 9, 2017, petitioner once again related his shoulder pain to the flu vaccine by reporting "left shoulder pain that began in fall 2016 after getting a vaccination, pain worsened as time passed." Pet. Ex. 4 at 33. His shoulder has ached since the shot." *Id*.

Dr. Schroeder argued that petitioner had not provided a "viable rationale" for why petitioner sought treatment for his right knee pain but did not seek treatment for his left shoulder pain. *See* Resp. Ex. C at 6. However, petitioner persuasively testified that his delay in seeking treatment for his left shoulder pain was because it was consistent with how he addressed other

injuries. In his affidavit, petitioner stated that he had "held out hope that whatever injury I had sustained would eventually heal itself….I have been an athlete my entire life playing varsity hockey and participating in mixed martial arts. It is not my nature to complain about pain. I was taught to push through the pain." Pet. Ex. 7 at ¶ 6. Consistent with his affidavit, petitioner testified that he had also delayed treatment for his right knee pain, and only went to get it examined at his wife's urging. Tr. 17, 23. Petitioner testified that it was a long time between when [he] first started experiencing the knee pain and when he finally got his knee examined and even then, he had done so at the urging of his wife. Tr. 23. He also testified that he had used ibuprofen and ice to alleviate the pain in his right knee. *Id.* The credibility of petitioner's testimony that he tended to put off seeking medical treatment for pain, was reinforced by the fact that when he did seek treatment for the knee it was discovered that he had a torn meniscus requiring surgical repair.

Similarly, delaying treatment for his left shoulder pain, petitioner testified, "I figured the pain would stop." Tr. 17. He explained that he used Advil and ice daily to treat his left shoulder pain. Tr. 14. He testified that his wife "was the catalyst to push me to go do something about [the left shoulder]," after she had noticed him using ice and not sleeping on his left shoulder. Tr. 17. When petitioner was asked if he had mentioned his left shoulder pain to his physical therapist, he testified, "I actually did mention it to them, but they were just primarily focused on the knee. And I brought it up a few times to them. I don't know the exact nature of referrals, but I was there for my knee, and I think that's what they were focused on." Tr. 32. As the medical records indicate, petitioner was referred to ProEx Physical Therapy for "pain in the right knee." *See* Pet. Ex. 4 at 5. The records demonstrate that the physical therapy was solely focused on treating petitioner's right knee pain. *Id.*

In *Kirby*, the Federal Circuit clarified *Cucuras*, stating, "We did not hold that medical records are presumptively accurate and complete. Nor did we state that when a person is ill, he reports all his problems to his doctor, who then faithfully records everything he is told. We reject as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). The Circuit held that a reasonable fact finder could find that petitioner's testimony of ongoing pain did not conflict with the records as the records are also silent about the *nonexistence* of such symptoms. *Id.* at 1383. Following *Kirby*, a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition. *See Kirby*, 997, F.3d 1378. The fact that the physical therapy records from October through December 2016 do not mention left shoulder pain does not conflict with petitioner's testimony that he had left shoulder pain from the flu vaccine, as these records were silent about the nonexistence of such symptoms. Petitioner was referred to the physical therapist for right knee pain, and thus treated for right knee pain, while at the same time believing his left shoulder pain would not need medical attention. Additionally, petitioner testified that he had mentioned his left shoulder pain during the physical therapy sessions, but it was not recorded as the focus of the physical therapy referral was for knee pain. Tr. 32.

Additionally, a delay in seeking treatment or a failure to report symptoms to a physician during an appointment for other issues is not necessarily dispositive of whether a petitioner's symptoms began within the appropriate timeframe. *See Stephens v. Sec'y of Health & Human*

Servs., No. 19-1685V, 2021 WL 482355 (Fed. Cl. Spec. Mstr. Sept. 15, 2021) (finding that petitioner's onset of pain was within the appropriate timeframe with a 70-day delay in seeking treatment for a SIRVA); *McGee v. Sec'y of Health & Human Servs.,* No. 18-1778V, 2021 WL 6059588 (Fed. Cl. Spec. Mstr. Nov. 30, 2021) (finding onset of shoulder pain within the appropriate timeframe with a five-month delay in treatment); *Desai v. Sec'y of Health & Human Servs.*, No. 14-811V, 2020 WL 4919777 (Fed. Cl. Spec. Mstr. July 30, 2020) (finding petitioner had established onset of pain within 48 hours of vaccination even though she delayed treatment for three months); *see also Forman-Franco v. Sec'y of Health & Hum. Servs.,* No. 15-1479V, 2018 WL 1835203 (Fed. Cl. Spec. Mstr. Feb. 21, 2018); *Tenneson v. Sec'y of Health & Hum. Servs.*, No 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019); *Gurney v. Sec'y of Health & Hum. Servs.,* No 17-481V, 2019 WL 2298790 (Fed. Cl. Mar. 19, 2019).

In this case, the testimony provided by witnesses was consistent with one another and consistent with the medical records that the onset of petitioner's pain began immediately after the vaccination, well within 48-hours of receiving the intradermal flu vaccination on September 7, 2016. Even though petitioner delayed medical care for his shoulder until the pain persisted for four months, all subsequent records with physicians and physical therapists consistently attribute the onset of pain to a reaction to the flu shot beginning with the injection. Additionally, the medical records also demonstrate that petitioner consistently related the onset of his pain to the flu vaccine he received in September 2016 and there is no record that is inconsistent with that history. Therefore, I conclude that testimony and medical records credibly and persuasively establish that petitioner's shoulder pain began immediately after the vaccination in question and continued to be painful for a considerable period of time, in excess of six months.

V. Causation Legal Standard

The Vaccine Act was established to compensate vaccine-related injuries and deaths. §10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity." *Rooks v. Sec'y of Health & Hum. Servs.,* 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

To receive compensation through the Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec'y of Health & Hum. Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that he suffered a Table Injury, he must prove that a vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her injury ("*Althen* Prong Three"). § 13(a)(1); *Althen*, 418 F.3d at 1278. In this case, petitioner is not alleging a Table Injury, as the Table designation is

limited to vaccines intended for intramuscular injection. Thus, petitioner must demonstrate that the vaccine was the cause of his shoulder injury.

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also *Pafford v. Sec'y of Health & Hum. Servs.,* 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Recently, in *Kottenstette,* the Federal Circuit reiterated that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.,* --Fed.Appx.—(Fed. Cir. June 15, 2021) (citing *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994). Causation "can be found in vaccine cases….without detailed medical and scientific exposition of the biological mechanisms." *Knudsen,* 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1325 (Fed. Cir. 2010).

Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Vaccine Program cases, the *Daubert* analysis

has been used in the weighing of the scientific evidence actually proffered and heard rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (Fed. Cl. 2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. *See, e.g.*, *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009).

Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

VI. Causation Analysis

a. *Althen* prong one

Under *Althen* prong one, the causation theory must relate to the injury alleged. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. It must only be "legally probable, not medically or scientifically certain." *Id.* at 549. However, the theory still must be based on a "sound and reliable medical or scientific explanation." *Id.* at 548. The Federal Circuit explained in *Althen* that "while [that petitioner's claim] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, *a sequence hitherto unproven in medicine*, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen,* 418 F.3d at 1280 (emphasis added).

1. Background on the intradermal flu vaccination

According to the Fluzone intradermal Quadrivalent package insert ("package insert"), the intradermal quadrivalent flu vaccine is intended for adults 18-64 years of age and contains 0.1 ml of fluid. Resp. Ex. C Tab 2. The insert notes that the "preferred site of injection is the skin in the region of the deltoid." *Id*. at 2. The microneedle injection system, pictured below, uses a hollow microneedle that "penetrates 1.5 mm into the skin from the outer skin surface." Resp. Ex. C at 7. The vaccine administrator is to hold the device perpendicular to the skin, between the thumb and middle finger, keeping the index finger free to compress the plunger. Resp. Ex. C Tab 2 at 3-4. The packet insert explains, "because the vaccine is injected into the skin, a wheal (superficial bump) and/or redness may be visible at the injection site." *Id*. at 4. In a controlled safety and immunogenicity study of the Fluzone Intradermal Quadrivalent vaccine, 53% of recipients reported pain at the injection site within seven days of vaccination, compared to 48% of those who received an intradermal trivalent flu vaccine. *Id.* at 8. Additionally, 11% of those that reported pain at the injection site who received the Fluzone Intradermal Quadrivalent characterized the pain as having "some or significant interference with daily activities." *Id*. at 9. This was compared to 9% who received the intradermal trivalent flu vaccine. *Id*. Further, 19% of participants who receive the Fluzone Intradermal Quadrivalent vaccine reported swelling at the injection site, compared to 14% who received the other intradermal vaccinations. *Id*.

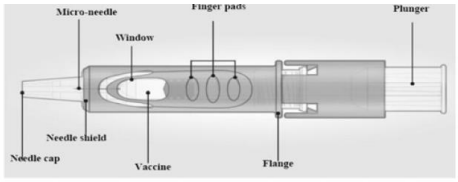

Figure 1. Diagram of micro-injector used to administer Fluzone Intradermal Quadrivalent vaccine. (*2*)

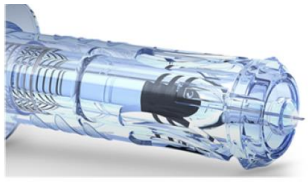

Figure 2. Typical flu shots are intramuscular, which means they go through the skin, a layer of fat, and then the muscle. Intradermal vaccines are injected into the skin through a small, ultra-thin needle (*3*).

Resp. Ex. C at 7.

Petitioner also submitted a Vaccine Administration Comparison Sheet, which gave an overview of the difference between intramuscular and intradermal administration. Pet. Ex. 29. The fact sheet demonstrated that the injection site for the Fluzone intradermal vaccine is intended to be perpendicular to the deltoid region of the arm, the vaccine administrators should place their index finger on the plunger to lightly pierce the skin and "apply very little pressure." Id. at 3. Further, it showed that when the plunger is fully depressed the vaccination is complete. To dispose of the device the vaccine administrators should use their thumb to "firmly push on the plunger to activate [the] needle shield." *Id*.

The *Lambert et al.,* article, submitted by respondent, explained that the skin was recognized "as a potentially excellent site for vaccination," because, in part, it "has both cellular and humoral immune system components." Resp. Ex. C Tab 1.[18] Further, the article noted that, "intradermal influenza vaccination in elderly subjects (0.1 ml dose) induced a humoral immune response superior to the [intramuscular] control against all three strains." *Id*. at 3. The *Rosenbaum et al.,* article, submitted by petitioner, explained that that "skin is an ideal target for vaccine injection due to the diversity of resident and recruited immune cells, including macrophages, Langerhans cells, and several subsets of dermal dendritic cells." Pet. Ex. 19. The authors found "a strong early local and systemic inflammatory response that peaked at 24 hours post-vaccination, which was the progressively replaced by an adaptive response." *Id.*

2. Discussion and Conclusion of *Althen* prong one

Petitioner's experts opined that the intradermal flu vaccine was mis-administered resulting in an inflammatory response in and around the structures of the shoulder that manifested as immediate pain and reduced mobility of the left shoulder. *See* Pet. Ex. 24 at 2; Pet. Ex. 11 at 6; Pet. Post-Hearing Brief at 9. Respondent argued that the 1.5 mm needle used for the intradermal flu vaccination could not directly penetrate the subdeltoid/subacromial bursa, and therefore, could not have caused petitioner's left shoulder pain and dysfunction. *See* Resp. Post Hearing Brief at 13-15; Tr. 140-142; Resp. Ex. C Tab 3 at 1; Resp. Ex. A Tab 11 at 1. Respondent asserted that even if the vaccine was administered improperly, the needle is not sufficiently long to deliver the antigen into the bursa. *Id.* at 13-14. Respondent's experts also argued that petitioner only had a local reaction, outside the shoulder anatomy, that cannot explain shoulder symptomatology. Resp. Post-Hearing Brief at 11; Tr. 82-86.

Petitioner has provided a sound and reliable theory which demonstrates how the intradermal flu vaccine, administered improperly, initiated an inflammatory response in and around the structures of his left shoulder, sufficient to induce pain and shoulder dysfunction.

Petitioner's expert, Dr. Huffman asserted that the improper vaccination technique used by the vaccine administrator injected the vaccine "deeper than was intended," below the dermal layer, and into the shoulder structure near the bursa, causing an inflammatory response, which led to shoulder pain and reduced range of motion. Pet. Post-Hearing Brief at 11-12; Tr. 113-15. Dr. Huffman testified that the needle has a "fixed length" of 1.5 mm and the skin can be as "thin

[18] Lambert, P. and Laurent, P., *Intradermal vaccine delivery: Will new delivery systems transform vaccine administration?* 26 Vaccine 3197-3208 (2008). [Resp. Ex. C Tab 1].

as 3 millimeters." Tr. 107. He opined that "with force" the needle could "get to a depth of close to a centimeter." *Id.* Dr. Huffman stated, "….I suspect that this went in quite a ways deeper than it was intended, possibly more than a centimeter or more." *Id.* He testified that he had reviewed the testimony from the vaccine administrator, Ms. Dell'Orfano, and stated "clearly the device was not properly used and too much force was used to administer [the vaccine]." *Id.* at 108. Dr. Huffman analogized the misadministration of the intradermal vaccine to a thumbtack being pressed into the skin stating, "…if I were to take a thumbtack and push it into the side of someone's shoulder, it would stop at the skin depth of a centimeter. However, if I push with more force, the investing skin and soft tissue would also indent, and the needle would go further and further as I pushed harder and harder." Tr. 110. Additionally, Dr. Huffman explained that the vaccine antigen that is being injected "extrude[s] out from the needle in a fair way," when the needle is injected with force. Tr. 127. He stated, "…If I [inject with a needle] more forcefully and suddenly, not only will the skin indent, but that fluid will be pushed several millimeters deeper than the actual needle." *Id.*

The testimony of the vaccine administrator, Ms. Dell'Orfano, supports Dr. Huffman's opinion that the intradermal vaccine was improperly administrated, injecting the antigen further than the intended dermal layer. Tr. 59-63; *see also* Resp. Ex. C, Tab 2. Ms. Dell'Orfano explained that the flu season of 2016 was the first time she was "regularly administrating intradermal vaccinations." Tr. 56. She also stated that administering the Fluzone on September 7, 2016 would have been early in the time in which she began using the intradermal vaccine. Tr. 64. During her testimony, Ms. Dell'Orfano demonstrated that she would "use her thumb" to press the injector when the injector system was against a patient's skin. Tr. 58-59. She also testified that you would need to use "a little bit of pressure because you have to hear that click to know that the medication actually went into the patient." Tr. 59.

A review of the instructions for administration on the Fluzone package insert, indicate that Ms. Dell'Orfano did not understand or follow those instructions. First, the package insert demonstrates the intended use of the intradermal injection directing to "position the device in your hand between the thumb and middle finger, keeping the index finger free." Resp. Ex. C, Tab 2 at 3. The vaccine administrator is to "Hold the device by placing the thumb and middle finger on the finger pads above device window. Keep the index finger free." *Id.* at 4. As depicted below, the vaccine administrator is to "gently pierce the skin perpendicular to the deltoid region," using "*light pressure.*" *Id.* (emphasis added).

Id. at 4. Then, "using index finger, gently press the plunger to inject the vaccine." *Id.* The package states that only once the needle is removed from the skin, the vaccine administrator is to

"push very firmly with the thumb on the plunger to activate the needle shield." *Id.* As Ms. Dell'Orfano demonstrated during the hearing, she held the device such that she used her thumb to press firmly down on the plunge, contrary to the instructions directing the vaccine administrator to use an index finger and "gently press the plunger". Tr. 59-60. Further, she stated that she pressed the plunger until she heard a "click." Tr. 60. However, the instructions provides that "When the plunger stop, vaccination is complete….Excessive pressure on the plunger may prematurely activate the needle shield on the patient's arm." Resp. Ex. C, Tab 2 at 4. Only when disposing of the injection system do the instructions indicate that the vaccine administrator should use their thumb and would hear a "click." *Id.*

In addition to the improper vaccination technique used by Ms. Dell'Orfano, petitioner testified that he was sitting, while Ms. Dell'Orfano was standing. Tr. 8. Further, petitioner testified that the vaccine was injected "on the left shoulder, kind of high, mid to back. *Id.* Petitioner pointed to an area approximately an inch and half below his acromion bone. *Id.* The *Atanasoff* article explains that "while patients are often seated for vaccinations, the standing position of the provider administering the injection may also contribute to injecting inadvertently high…" Resp. Ex. A, Tab 9 at 4. The article also noted that approximately half of patients in their case series "reported vaccine administration "too high" in the shoulder," and the authors opined that "in some of our cases the injury may have been the result of improper injection technique." *Id.*

Respondent's expert, Dr. Cagle, conceded that Ms. Dell'Orfano administered the vaccine inconsistently with the instructions provided on the package insert. Tr. 151. Thus, the demonstration and testimony of Ms. Dell'Orfano about the technique she used in comparison to the instructions from the package insert, the seated position of petitioner during vaccine administration, and the location in which petitioner received the vaccine sets forth a sound basis for concluding that it is likely that there was overpenetration and deposition of the vaccine into the tissue beneath the skin.

Dr. Huffman explained that the likely place the intradermal vaccine was administered was into the hypodermis layer, which is an area "prone to inflammation." Tr. 129. He testified that the hypodermis layer is not the surface layer, but soft tissue, which has a "rich blood supply in lymphatics," and when the vaccine was injected into this area, it could cause pain. *Id.* The *Lambert* article, filed by respondent and referenced by Dr. Huffman, depicts the skin anatomy, and indicates that the hypodermis layer sits approximately 3 mm to 100 mm below the skin surface, depending on body mass, body sites, age, and gender. Resp. Ex. C, Tab 1 at 3. Dr. Cagle's opined that it would be "virtually impossible" for a 1.5 mm needle to penetrate the deltoid muscle and that a needle would need to be at least 1 centimeter long to reach the deltoid layer. Tr. 143-44. However, petitioner's theory is *not* that the vaccine was injected into the deltoid, but instead, reached the hypodermis, which lays above the deltoid muscle, and only 3 mm below the surface of the skin. Further, consistent with Dr. Huffman's theory, the *Poland* article explained, "Use of shorter needles…resulted in deposition of vaccine into the subcutaneous tissue, which is well innervated with pain fibers compared with poorly innervated muscle tissue." Resp. Ex. A, Tab 11 at 3; Tr. 164. As is well documented in the evidence in this case, the intradermal needle was designed to be shorter than the traditional intramuscular needle and intended to deposit the vaccine material into the intradermal space. In the scenario that the

needle was pushed through the dermis with excessive force, the vaccine could easily be deposited in the subcutaneous tissue giving rise to pain and later shoulder dysfunction.

Petitioner's experts opined that the vaccine being injected into the hypodermal space caused both a local and regional inflammatory reaction, which led to shoulder pain and reduced mobility. Tr. 112. Dr. Gershwin stated, "It is well known that vaccination leads to firstly a local immune response within the nearby lymphatics, which will then traffic through the interstitium through other lymph nodes." Pet. Ex. 24 at 1. He stated that, "It is also well known that reactions can lead to significant swelling, and this is part of the systemic reaction. In other words, the response to vaccination includes an inflammatory response. This inflammatory response, like any other mechanical event, can obstruct or impinge on adjacent tissues, including the bursa, tendon, and local nerves." *Id.* Consistent with Dr. Gershwin's opinion, Dr. Huffman testified that vaccines are "meant to engender a broader systemic inflammatory and immunologic response," but the vaccine can also elicit a local inflammatory response. Tr. 112. Dr. Huffman testified that there is an "early inflammatory response that's expected and hoped for," through vaccination, but that petitioner also had a local response as evidenced by petitioner's description of the hardened area where he received the vaccine. *Id.* Dr. Huffman observed that the reported local adverse reactions to the intradermal vaccine were more common than the intramuscular flu vaccine. Tr. 124. The package insert provides that 76.4% of intradermal vaccine recipients had injection-site erythema, compared to 13.2% of patients who received the intramuscular flu vaccine. Resp. Ex. C, Tab 2 at 10. Injection-site induration, injection-swelling, and injection-site pruritis were also elevated compared to the intramuscular flu vaccinations. *Id.* The incidence of pain was found to be equal to that seen in intramuscular injections. *Id.*

Respondent's expert, Dr. Schroeder agrees that the intradermal vaccine can elicit a systemic reaction, but he argued that petitioner's experts did not demonstrate how a systemic inflammatory response could result in an inflamed shoulder. Resp. Ex. C at 8. However, during the hearing, Dr. Schroeder conceded that petitioner likely had a "local reaction" to the intradermal vaccine. Tr. 86. He argued that petitioner had "local inflammation that occurred as a result of the injection with local pain at the injection site," but then the petitioner's decreased range of motion and decreased strength was only because of degenerative changes in petitioner's shoulder and possibly the petitioner's lifestyle. *Id.* Dr. Schroeder offered a similar argument in *Lagle,* in which he conceded that the intradermal caused a local inflammatory response, but that the changes in the petitioner's shoulder was totally unrelated to the vaccination. *See Lagle v. Sec'y of Health & Human Servs.,* No. 16-1053, 2022 WL 2299003, at * 30 (Fed. Cl. Spec. Mstr. May 25, 2022). Like in *Lagle,* Dr. Schroeder's opinion that the vaccination was simply coincidental to the onset of petitioner's pain and shoulder dysfunction, even with evidence of a local inflammatory event, is not credible as it fails to account for the lack of any prior shoulder symptoms and the immediate onset of pain after the vaccination.

Dr. Huffman opined that petitioner's symptoms were most consistent with rotator cuff inflammation or bursitis in the subacromial space. Pet. Ex. 11 at 5; Tr. 115. Dr. Huffman observed that petitioner did not experience any symptoms related to shoulder dysfunction prior to the vaccination. Pet. Ex. 11 at 5. Dr. Huffman explained that petitioner's MRI showed some other pathology, but that "there was no real clear documentation that those things were actually bothering [the petitioner]." Tr. 115. Dr. Huffman testified that it was common for people the

same age as the petitioner to have asymptomatic rotator cuff pathology. Tr. 130. Dr. Cagle agreed with Dr. Huffman, that degenerative changes in the shoulder can be found on MRIs which are unrelated to the symptoms of post-vaccination shoulder pain. Tr. 144-45. However, Dr. Cagle argued that petitioner had "pre-existing shoulder pain," and that the identified shoulder pathology became "clinically relevant," at some point after the intradermal flu vaccine, but without identifying another inciting event. *Id.* at 148. The *Atanasoff* article explains, "Although shoulder dysfunction due to mechanical or overuse is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination….is consistent with a robust and prolonged immune response with already-sensitized shoulder structures following injection of antigenic substance." Pet. Ex. 12 at 3; Resp. Ex. A, Tab 9. The authors theorized that some of the MRI findings in their patients, such as rotator cuff tears, "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." *Id.* at 3. Dr. Huffman opined that the intradermal vaccine, administered incorrectly, caused an inflammatory reaction in the area around the pre-existing shoulder pathology, it could lead to pain, resulting in a reduced range of motion. Tr. 130-31. Dr. Cagle also conceded shoulder injuries from post-vaccination administration manifest in "pain."

The petitioner's experts did not argue that the intradermal vaccination can cause an underlying rotator cuff tear, but that the intradermal vaccine can cause local and regional inflammation that resulted in pain and reduced shoulder motion. The authors in *Atanasoff* recognized that asymptomatic shoulder pathology may pre-exist vaccination but observed that the prompt onset of pain after vaccination is consistent with a robust and prolonged immune response with already-sensitized shoulder structures following injection of antigenic substance. *See* Pet. Ex. 12 at 3. The *Poland* article discussed the presence of abundant pain fibers in the subdermal or hypodermal space that can give rise to pain when a vaccine is deposited into that space. The explanation by Dr. Huffman that the application of even a fairly slight amount of excess pressure during the intradermal vaccine administration, as appeared to be well demonstrated by Ms.Dell'Orfano, could readily compress the skin and other soft tissue and allow penetration beyond the dermis into this pain sensitive area provides a sound and reliable explanation of the way an intradermal flu vaccine can cause inflammation in the shoulder structure that results in pain and shoulder dysfunction. Further, the package insert also found that the reports of pain at the injection site with an intradermal injector is equal to that seen in intramuscular injections. *See* Resp. Ex. C, Tab 2 at 10.

Thus, the respondent's argument that the needle must penetrate deep into the structure of the shoulder to cause shoulder pain is sufficiently rebutted by the explanation of excess pressure compressing the skin and adipose tissue during the injection allowing penetration well beyond the intradermal space. Further, Dr. Huffman's explanation that when that occurs the fluid may penetrate well beyond the length of the needle into the highly innervated soft tissue is also instructive. The occurrence of such penetration high in the arm where structures like the bursa are closest to the skin, also makes more likely the spread of inflammatory pain in the region of shoulder structures.

For all of the above reasons I conclude that petitioner has presented a reputable scientific theory based on a sound and reliable medical explanation explaining how the flu vaccine

administered with the intradermal injector can cause shoulder pain and dysfunction, thus satisfying *Althen* prong one.

b. *Althen* prong two

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [her] injury." *Althen*, 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen*, 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Hum. Servs.,* 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148.

Petitioner's experts opined that the intradermal flu vaccine caused a local and regional inflammatory response after being mis-administered. Pet. Post-Hearing Brief at 12. The flu antigen being administered into the hypodermal layer, below the dermal layer, caused an inflammatory immune response which led to pain and reduced range of motion secondary to pain. Tr. 129-30. Dr. Huffman testified that the inflammation led to petitioner having rotator cuff tendinopathy and bursitis. Pet. Ex. 11 at 5.

Both Drs. Schroeder and Cagle opined that the 1.5 mm needle was not sufficiently long to cause petitioner's shoulder pain and reduced mobility. *See* Resp. Ex. A at 4; Resp. Ex. C at 10. Dr. Schroeder stated that depth of the skin is between 2 to 4 mm in length and that the 1.5 mm needle "in no way can enter into the joint space," and cause a local immune response that leads to joint pain. Tr. 77. Dr. Cagle stated, "I don't think it's possible for a 1.5 mm needle to press through those layers of tissue," and opined that "…the muscle, the adipose tissue layer, and the bursa would all somehow have to be compressed down to less than 1.5 mm," for the needle to penetrate further than the layers of skin. Tr. 141-42. Further, Dr. Schroeder asserted that the intradermal flu vaccine applicator was designed to be "less sensitive to operator error. Tr. 89. Additionally, Dr. Schroeder argued that the petitioner's local reaction was a "common local side effect from intradermal injections." Tr. 84. Dr. Schroeder asserted that some of the local reactions to the intradermal flu vaccine, like erythema, redness, swelling, induration and hardness, can be caused "on an irritant basis," or "as a result of innate immune response." Tr. 84-85. However, he argued that the local inflammatory reaction could not cause tendonitis. *Id.* Instead, he argued that petitioner's decreased range of motion and decreased strength was more likely a result of "definitive evidence of degenerative changes that can occur to anyone and certainly someone who is as active as [petitioner]." Tr. 86. Dr. Cagle also implied that petitioner's shoulder pain was more related to "chronic-style wear and tear degenerative changes," that were present on petitioner's MRI and that it became "clinically relevant later." Tr. 148. It was his opinion that the intradermal vaccine could not exacerbate underlying shoulder pathology, making it painful.

Dr. Huffman concluded that the intradermal flu vaccine could be administered deeper than the intended dermal layer and deposited into the hypodermal layer, causing pain. Dr. Huffman opined that when a needle is "inject[ed] with force, it's going to extrude out from that needle in a fair way." Tr. 127. Further, he testified that if more force is used on the needle and it is injected suddenly, "not only will the skin indentate, but that the fluid will be pushed several millimeters deeper than the actual needle." *Id.* He stated that the vaccine could be inadvertently administered into the hyodermis or "the adipose layer," which is an area prone to inflammation." Tr. 129. He observed that the *Lambert* article, showed that the dermis layer is approximately 1.5 mm to 3 mm thick, with the hypodermis directly beneath the dermal layer. Resp. Ex. C, Tab 1 at 3. The *Poland* article also explains that the "use of shorter needles" in intramuscular vaccines, "resulted in the deposition of vaccine into the subcutaneous tissue, which is well innervated with pain fibers compared with the poorly innervated muscle tissue." Resp. Ex. A, Tab 11 at 3. Dr. Huffman stated that it was likely that most of the vaccine was delivered into the hypodermis area on the petitioner, which caused petitioner pain. Tr. 130.

Additionally, the vaccine administrator, Ms. Dell'Orfano, testified that the first time she had administered the intradermal flu vaccine was in 2016. Tr. 56. She stated that September 7th would have been "early in the time" that she had been using the intradermal vaccines. Tr. 64. Ms. Dell'Orfano stated that when administering the intradermal vaccine she had to use "a little pressure" because the administrator had to "hear the click to know that the medication actually went into the patient." Tr. 60. When she demonstrated how she administered the intradermal vaccines, she used her thumb to press on the injector. *Id.* As discussed above, the way that Ms. Dell'Orfano described how she administered the Fluzone intradermal vaccine was inconsistent with directions provided in the package insert. Respondent's expert, Dr. Cagle, also conceded that Ms. Dell'Orfano testimony regarding the administration of the vaccine was "inconsistent" with the directions included in the package insert. Tr. 153; *see also* Resp. Ex. C, Tab 2 at 3-4.

Further, petitioner testified that Ms. Dell'Orfano was standing while he was seated during the vaccination. Tr. 8. Petitioner also stated that the vaccine was "on his left shoulder, kind of high, mid to back." *Id.* As explained in the *Atanasoff* article, about half of the patients who experienced post-vaccination shoulder pain indicated that the vaccination was "too-high." Resp. Ex. A Tab 9. Further, the article states that "while patients are often seated for vaccinations, the standing position of the provider administering the injection may also contribute to injecting inadvertently high into the deltoid." Resp. Ex. A Tab 9 at 4. Given that the vaccine was administered high on petitioner's left shoulder while he was seated, the microinjector was relatively new technology to the vaccine administrator, and Ms. Dell'Orfano's demonstration of how she administered the vaccine was inconsistent with the package instructions, support a misadministration of the vaccine where the antigen was deposited below the dermal layer and resulted in an inflammatory reaction that caused pain and reduced shoulder mobility.

Dr. Huffman opined that the vaccine, being administered below the dermal area, into the hypodermal space, was the cause of petitioner's pain and reduced shoulder mobility. Tr. 129-30. Dr. Huffman observed that petitioner had a hardened area where the vaccine was administered on his left shoulder. Tr. 112. Further, he stated that if the vaccine was placed into a space with proximity to the shoulder structures, such as the bursa, it can create bursitis or an inflammatory

response in the bursa. Tr. 113. Dr. Huffman opined that petitioner's symptoms were "most consistent with rotator cuff inflammation or bursitis in the subacromial space." Tr. 115.

Dr. Schroeder agreed that petitioner had a local inflammatory reaction at the site of vaccine injection. Tr. 93. However, Dr. Schroeder contended that the "local inflammation that occurred as a result of the injection was consistent with local pain at the site of injection," did not extend into the [shoulder] joint itself, causing decreased range of motion. Tr. 86. Dr. Schroeder offered a similar opinion in *Lagle,* another intradermal Fluzone case. *See Lagle v. Sec'y of Health & Human Servs.*, No. 16-1053, 2022 WL 2299003, at *31 (Fed. Cl. Spec. Mstr. May 25, 2022). In *Lagle,* Dr. Schroeder also argued that the petitioner had a local reaction to the vaccine, but that the petitioner's reduced shoulder mobility was "totally unrelated to the vaccination," despite being unable to identify specific evidence that would have caused a previously asymptomatic rotator cuff tear to become painful. *Id.* In this case, Dr. Schroeder offers an almost identical opinion, stating that "the complaints of decreased range of motion and decreased strength, and then…the results of the MRI is definite evidence of degenerative changes that can occur to anyone and certainly someone who is as active as [petitioner] has been. So I think it's just a coincidence that the pain in the shoulder is associated temporally with the injection that he received." Tr. 86. As in *Lagle,* I find Dr. Schroeder's opinion that that petitioner's prolonged local inflammatory response was simply coincidental to his shoulder dysfunction unpersuasive. Dr. Schroeder's speculative opinion fails to account for petitioner's lack of pain in that shoulder prior to the injection and then immediate pain thereafter.

Dr. Cagle argued that petitioner's shoulder injury was inconsistent with a post-vaccination shoulder injury because there was no increased fluid signal in the bursa and that he "did not see any signs of a diffuse inflammatory rotator cuff response," on petitioner's MRI. Tr. 145. He agreed with Dr. Schroeder's opinion that local inflammatory reaction (which Dr. Cagle characterized as a "localized skin irritation), could not cause rotator cuff tendinopathy. Tr. 148. However, Dr. Cagle conceded that petitioner had an initial local inflammatory response to the vaccine that began immediately after the vaccination. Tr. 170. Additionally, in response to questions from the Court, Dr. Cagle stated that "a localized inflammatory pain" can cause a person to guard or reduce range of motion. Tr. 171-72.

As both Drs. Huffman and Schroeder observed, the Fluzone package insert provides that the Fluzone intradermal vaccine causes injection-site induration, swelling, pruritus and erythema at significantly higher rates compared to an intramuscularly administered flu shot. *See* Resp. Ex. C, Tab 2 at 10. Induration, pruritus and erythema are all caused by some type of inflammatory reaction. Additionally, "injection-site pain" was reported at approximately the same rate as the intramuscular flu shot. *Id.* Further, the *Atanasoff* article explained, "Although shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination….is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into…the area around the rotator cuff tendon." Resp. Ex. A, Tab 9 at 3. Here, there is credible evidence that the vaccine was mis-administered and likely resulted in the deposit of the antigen below the dermal layer high on the shoulder where the bursa are closest to the surface causing an inflammatory reaction in the shoulder area Drs. Huffman and Gershwin also explained, which Dr. Schroeder did not dispute, that the vaccine is intended to

cause a systemic immunological reaction in order to offer the person receiving the vaccine immunity. *See* Pet. Ex. 24 at 1; Resp. Ex. C at 9. Dr. Gershwin opined that the local inflammatory response "can obstruct or impinge on adjacent tissues, including the bursa, the tendon, and the local nerves." Pet. Ex. 24 at 1. As Dr. Huffman explained, petitioner's symptoms best reflected inflammation of the rotator cuff or bursitis in the subacromial space near where the injection was given high in the arm just below the end of the acromion. Tr. 115; Pet. Ex. 11 at 5.

Prior to receiving the vaccine, petitioner did not experience shoulder pain and dysfunction that impacted his quality of life. Tr. 130. Petitioner received the intradermal flu vaccination on September 7, 2016. Pet. Ex. 1; Tr. 11-12. He recalled that when he arrived at the appointment on September 7, 2016, he was not experiencing any left shoulder pain, and when he left the appointment, his pain was at a 9 on a scale of 1-10. He immediately took pain medication and iced his left shoulder. *Id*. at 10. Petitioner testified that after he left the appointment his shoulder "felt just like getting stung by a large bee, and it felt like the stinger was still in my arm." Tr. 9. That evening petitioner "could still feel the stinging in my arm and I continued to toss and turn." Tr. 10.

On January 20, 2017, petitioner was seen by his primary care physician, Dr. Powell with complaints of left shoulder pain, relating the pain to the flu vaccination he received on September 7, 2016. Pet. Ex. 1 at 14. The physical exam noted "limited range of motion with concerns of possible rotator cuff injury from the influenza vaccine." *Id*. at 17. Petitioner again related the pain in his left shoulder to the vaccination at an appointment with Dr. Gill on January 27, 2017, at which time it was noted that his pain was worsening despite conservative treatment. Pet. Ex. 2 at 6. Petitioner also underwent an MRI on January 27, 2017, because of his report of shoulder pain that began at the time of the vaccination. The MRI showed mild to moderate degenerative changes in different parts of the shoulder.

Petitioner participated in physical therapy for his shoulder from October 24, 2017, to December 19, 2017, and patient reported at physical therapy discharge that the "shoulder does not bother him during working out or daily tasks but still bothers him when he tries to fall asleep." Pet. Ex. 4 at 70. On January 18, 2018, "pain in left shoulder" was listed as a current problem, along with others. Pet. Ex. 1 at 2-7. During the hearing, petitioner testified that he "can still feel the pain in the shoulder" and it "feel[s] still like there's a bee stinger in my shoulder." Tr. 26. Petitioner testified that the pain caused him to limit his use of the arm and that he had difficulty with various activities such as reaching above the shoulder and sleeping. *See* Tr. 10, 17. Further, petitioner explained that his pain was localized to the "immediate area where he received the shot." Tr. 10.

Finally, Drs. Schroeder and Cagle opinion that the onset of petitioner's pain was unrelated to the intradermal vaccine is unconvincing. Dr. Cagle asserted that petitioner's left shoulder pain was more attributable to "chronic-style wear and tear degenerative changes [that] were present in the [petitioner's] shoulder" and that at some point later the petitioner's shoulder pathology became clinically relevant, but could not point to a specific injury or event in the record that would explain the onset of pain. Tr. 148. Dr. Schroeder averred that petitioner's shoulder pain "appears to be the consequence of tearing, degeneration, and inflammation in his

joints." Resp. Ex. C at 12. He stated, "A more likely explanation for his physical complaints is that he is suffering from the sequelae of pursuit of his athletic hobbies rather than the consequence of an intradermal vaccination." *Id.* at 12. During the hearing, Dr. Schroeder testified that the onset of petitioner's pain at the time of receiving the intradermal vaccine was a "coincidence." Tr. 86. Dr. Huffman acknowledged that petitioner likely had pre-existing shoulder pathology, but those issues, such as the glenoid labrum tear and degeneration within the acromioclavicular joint were "unrelated to the symptoms described by petitioner," and petitioner was not treated for those issues. Tr. 130; Pet. Ex. 11 at 5. Dr. Huffman stated that it was his understanding that petitioner never experienced left shoulder pain that affected his quality of life, disrupted his sleep, or for which he sought medical treatment prior to the intradermal vaccination. Tr. 130. The *Atanasoff* article explains that MRI studies of asymptomatic patients past middle age found that 39% of the patients had partial or complete rotator cuff tears. Resp. Ex. A, Tab 9 at 3. The article explains that these conditions can cause no symptoms until provoked by trauma or other events. *Id.* Thus, Dr. Schroeder and Dr. Cagle's opinions that petitioner's life-style or the underlying shoulder pathology "coincidentally" became symptomatic the day of the vaccination is unpersuasive as it fails to account for the prior lack of pain and the sudden onset of significant pain immediately after receipt of the vaccination. While the MRI demonstrated that petitioner had some degenerative conditions in his shoulder, the medical literature explains that many people of his age have similar conditions and they are often asymptomatic, as petitioner testified was true in his case. Speculation from respondent's experts that an underlying degenerative condition suddenly became symptomatic after the vaccination, but had nothing to do with the vaccination is unpersuasive when compared with the clear, consistent and logical history given by the petitioner and his wife and which is consistent with the medical records.

Petitioner presented evidence that the vaccine administrator failed to follow the proper vaccine administration instructions, likely leading to the deposition of the vaccine into the hypodermal space, resulting in both a local and regional inflammatory response that caused immediate pain and shoulder dysfunction. Accordingly, the petitioner has proven *Althen* prong two by a preponderance of the evidence.

c. *Althen* prong three

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has equated to the phrase, "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one). *Id.* at 1352.

Petitioner argued that the appropriate timeframe for a shoulder injury following the influenza vaccination is 48-hours. Pet. Brief at 13. Petitioner's expert, Dr. Huffman opined that petitioner suffered from an immediate local response, as demonstrated by the hardened area on petitioner's left shoulder that persisted for weeks, and that he also had a regional inflammatory

reaction. Tr. 112-13. Dr. Huffman also observed that the local adverse reactions that occurred within seven days of the intradermal vaccine being administered was "very high." Tr. 124.

Respondent argued that "petitioner inappropriately seeks the presumption the Vaccine Injury affords with regard to SIRVA claims to satisfy the third prong of *Althen.*" Resp. Brief at 16. Respondent stated that the petitioner attempted to "bootstrap" the elements for establishing a Table SIRVA claim to his off-Table shoulder injury claim." *Id.* at 7, n. 3. Respondent stated that "simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation." *Grant v. Sec'y of Health & Human Servs.,* 956 F.2d 1144,1147-48 (Fed. Cir. 1992).

As discussed above, petitioner established by preponderant evidence that his pain began immediately after receiving the intradermal flu vaccine. Petitioner's expert, Dr. Huffman, stated that petitioner's shoulder pain was immediate after the vaccination he received on September 7, 2016. Pet. Ex. 26 at 2. Both of respondent's experts also acknowledged that petitioner's pain began immediately after the intradermal vaccination. Tr. 86, 153. Indeed, respondent's expert, Dr. Schroeder asserted that a "local inflammatory reaction would likely occur within 24-48 hours" of an intradermal vaccination. Tr. 83. Further, Dr. Schroeder acknowledged that petitioner had pain associated at the site of the injection immediately following the vaccination. Tr. 86.

Additionally, the Fluzone Intradermal package insert vaccine explains that 76% of vaccine recipients experienced injection-site erythema within seven days of receiving the vaccination, 51% reported injection-site pain, and 56% of vaccine recipients reported injection-site swelling. The *Atanasoff* article also explained that the 93% of patients with post-vaccination shoulder injuries reported the onset of pain as occurring less than 24 hours after vaccination and 54% of the cases reported that the pain began immediately. Pet. Ex. 12 at 2. Additionally, Dr. Huffman and Dr. Gershwin credibly explained that the intradermal vaccine can lead to a larger systemic reaction that generates an inflammatory response. *See* Pet. Ex. 24 at 1. The package insert establishes that the occurrence of pain within seven days post-vaccination as a medically acceptable timeframe to establish that the intradermal flu vaccine can cause an inflammatory reaction that leads to pain and shoulder dysfunction.

Finally, a similar timeframe between the intradermal flu vaccination and the onset of shoulder pain and dysfunction have been in accepted in two other cases. *See Lagle,* 2022 WL 2299003, at *33; *Allen v. Sec'y of Health & Human Servs.* No. 15-1278, 2022 WL2255042, at *24-25 (Fed. Cl. Spec. Mstr. June 2, 2022) (accepting a 48-hour timeframe between onset of petitioner's shoulder pain and reduced range of motion and receipt of the intradermal flu vaccination).

In this case, the medical records, the testimony of the petitioner and his wife credibly established that petitioner experienced significant pain at the injection site immediately after the shot was given. The expert testimony from both parties acknowledged that petitioner experienced a local inflammatory reaction well within the timeframe established in the package insert and experts from both parties acknowledged that petitioner testified that he experienced pain immediately following the vaccination. There is no reason to suggest that the onset of pain

after an intradermal vaccination would occur in any time frame other than that even though the package insert allows for seven days. As such he has proven by a preponderance of the evidence that the timing of his injury was appropriate to demonstrate vaccine causation and has proven *Althen* prong three.

VII. Conclusions

For all the reasons discussed above, petitioner has established by preponderant evidence that he is entitled to compensation, demonstrating that the intradermal flu vaccine administered on September 7, 2016, was the cause-in-fact of his right shoulder pain and dysfunction. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master